

SELF-APPLICATION OF AN ANTICARIOGENIC PROPHYLAXIS
PASTE AS A TECHNIQUE FOR THE PARTIAL REDUCTION OF DENTAL
CARIES PERFORMED ON A MASS TREATMENT BASIS

by

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INTRODUCTION

Introduction

Dental caries is not the only oral health problem about which we are concerned, even though it is the most prevalent. Dental caries begins early in life! Soon after the primary molar erupts (at about 12 to 14 months), the tooth becomes susceptible to dental caries. It has been shown that¹ by two years of age about 40 per cent of children have at least two dental cavities. By six years of age the severity increases, and over 80 per cent of the children have tooth decay. Also the number of cavities has increased from two per child to about fourteen per child. When the children have reached about 12 years of age both deciduous and permanent teeth are involved, with the average child at this age having lost through dental caries about eight deciduous and two permanent teeth. The overall number of cavities (expressed as DMF surfaces) has increased to thirty per child.

This problem of dental caries does not end with the loss of deciduous teeth, but continues in prevalence as the permanent teeth erupt. In the U.S.A. the average number of new dental caries per child is about three new cavities in the permanent teeth.

The classic approach to the control of dental caries is by restoration of the defect with a suitable material. However, this is not the answer to the problem, because it is not only very costly, but the inadequacy of the number of dentists available to prevent the progression of caries remains a dominant factor. The ratio of population to dentists is approximately 2,000 to 1 in the United

States.²

So the need for a prophylactic measure which is effective, practical, safe and economical should be utilized. Dean³ and other investigators^{4,5} demonstrated that dental decay was partially controlled by the natural occurrence of fluoride in communal water supply. Studies beginning in 1945⁶⁻⁸ have confirmed the hypothesis that the benefit of natural fluoridation could be achieved with the supplementation of fluoride deficient water with fluoride compounds up to the optimum level. This would provide the same protection against dental caries as naturally fluoridated water. The benefit of communal fluoridation is limited to those children who live from birth in a fluoride area up to 10 to 12 years of their life, or who migrate early after birth to that area. Realizing the limitation of communal fluoridation, the profession has been trying to resort to other methods of utilizing fluoride. The other methods of using fluorides are either through systemic fluoride therapy as fluoride tablets (with or without vitamins), fluoride in dentifrices and prophylactic paste, or through topical fluoride applications. The topical action of fluorides is obtained either by topical application of concentrated fluoride solutions, by the dentist or dental hygienist or by the patients themselves using fluoride containing dentifrices.

The different fluoride compounds have been compared as to their effectiveness in reducing dental caries both in vitro, in vivo, and in clinical studies.⁹⁻²⁴ The most promising of these compounds has been shown stannous fluoride. This compound, when used in multiple

topical fluoride therapy (in compatable prophylactic paste, single topical applications of fluoride solution and the daily use of the $\text{SnF}_2\text{-Ca}_2\text{P}_2\text{O}_7$ dentifrice) in non-fluoride area in both children and adults, provides cummulative effects similar to communal fluoridation.^{25,26} In optimal fluoride areas the multiple fluoride therapy further provides additive benefits to communal fluoridation in both children and adults.^{27,28} But still these benefits will not be at the same low cost as offered by communal fluoridation, and besides it requires trained personnel to perform the treatments. The ambitious dental scientist is continually searching for other methods which would provide the benefit of fluoride at a very low cost, on mass basis, and which would be applied by the patients themselves.

This thesis is directed toward a partial solution to this problem of an excessive time factor and in developing a low cost form of fluoride therapy for preventing dental caries.

REVIEW OF LITERATURE

Review of Literature

Sodium Fluoride Containing Prophylactic Paste

Knutson²⁹ and Bibby³⁰ reported that when aqueous solutions of sodium fluoride were applied topically to freshly cleaned tooth surfaces of children, the activity of dental caries could be reduced. Bibby stated³¹ "Unfortunately this method was time consuming and the technique not usually used by dentist or dental hygienist". So Bibby and his co-workers in 1946 tried another method for topical treatment with fluoride which was more simple, and could be applied by the hygienist in the routine way of giving oral prophylaxis. They conducted clinical studies in which a 1.0 per cent sodium fluoride-pumice hydrogen peroxide mixture was used. The pH of the prophylactic mixture was approximately 4.0. The half-mouth technique was used. The right side (control) was cleaned by the hygienist with a mixture of pumice and hydrogen peroxide in the ordinary way using a rubber cup. The left side (experimental) was cleaned by the same hygienist in the same way by using the 1.0 per cent sodium fluoride-pumice hydrogen peroxide mixture. In this study three dental prophylaxis were given during the school year study period to 47 girls aged 6 to 14 years.

The clinical examination at the end of one year showed approximately 42 per cent less new decay on the treated side in comparison to the control side. Caries reduction in the deciduous teeth was 59 per cent less new cavities on the treated side (left) as compared to the control side (right).

In another study Bibby³⁰ used the same mixture and the same

technique. The study group included 95 children aged 6 to 15 years. The only difference was that two prophylaxis were given during the school year study period instead of three prophylaxis as used previously. At the end of one year there was 25 per cent less dental caries in the treated side than the control side. Caries reduction in the deciduous teeth was less marked than the permanent teeth, which was 21 per cent less new cavities in the treated side (left) than the control side (right). Bibby stated that the difference in the results was not fundamentally due to the number of treatments given.

A larger study³² was conducted with a 1.0 per cent sodium fluoride-pumice hydrogen peroxide mixture. The number of patients in this study were 250 children aged 10 to 12 years. Three prophylaxis were given annually. After one year no reduction in dental caries was found.

It has been suggested³³ that these negative findings were due to the presence of calcium carbonate in the abrasive used as the cleaning paste resulting in the formation of calcium fluoride.

Tusnova³⁴ reported on the use of a 75 per cent sodium fluoride prophylactic paste mixture using 869 children aged 7 to 14 years. The teeth on one side of the maxilla were treated twice a year and served as experimental group. Teeth on the other side served as controls.. In this study there was a 50 per cent reduction in dental caries in the treated teeth.

Kiseleva³⁵ reported negative results with the use of a 75 per cent sodium fluoride prophylactic paste mixture using a whole mouth technique. The treatment was repeated twice a year in 942 children aged 6 to 14

years. A total of 989 children served as the control group. No difference in the carious incidence was observed between the two groups.

In summarizing the results of these clinical studies utilizing a sodium fluoride prophylactic paste, the results seems to be contradictory.

Sodium Fluoride vs. Stannous Fluoride

It has been suggested that stannous fluoride is more active than sodium fluoride in reducing enamel solubility. Muhler, Boyd and Van Huysen⁹ determined the protective value of 32 reagents upon the solubility of powdered enamel, dentin and tricalcium phosphate in 0.2 molar acetic acid buffered to a pH of 4.0. From these 32 reagents, stannous fluoride was found more effective in reducing the solubility of enamel, dentin, and tricalcium phosphate. The superiority of stannous fluoride over sodium fluoride in reducing the solubility of whole tooth in weak organic acid was shown also by Ericsson.¹⁰

Radike and co-workers in 1956¹¹ studied the effect of stannous fluoride and sodium fluoride in reducing the enamel solubility of radioactive caries-free teeth at pH values ranging from 2.5 to 5.5. The results of these studies showed that stannous fluoride provided protection against acid decalcification more than twice that of sodium fluoride.

Segreto and his co-workers¹² determined the antisolubility effectiveness of various concentrations of stannous fluoride when topically applied to extracted human intact teeth. The loss of both stable and radioactive phosphorus caused by formic acid decalcification were measured. They reported that the protection was markedly increased

when the concentration was increased from 0 to 10 per cent but very slight increases in protection occurred at higher concentrations of 15, 20 and 25 per cent. The stannous fluoride provided about 80 per cent protection against acid decalcification when compared to the control group treated with water. Also, they reported more radioactive phosphorus was lost in decalcification following sodium fluoride application than with the control group treated with water. Further, they reported that equal mixtures of stannous fluoride and pumice as a prophylactic paste provided 50 to 60 per cent protection to formic acid decalcification.

Experimental dental caries studies in rats¹³⁻¹⁵ under a variety of different experimental conditions supported these in vitro findings and demonstrated the superiority of stannous fluoride over sodium fluoride. Similarly, experimental dental caries studies in hamsters¹⁶ supported the superiority of stannous fluoride over sodium fluoride.

Phillips and Swartz¹⁷ studied the enamel hardness of extracted human teeth before and after treatment with stannous fluoride. They found that teeth immersed in a 1:10,000 stannous fluoride mouthwash, buffered to pH 4.0 for five minutes, showed increased enamel hardness.

The same investigators¹⁷ used a 4.0 per cent stannous fluoride solution mixed with hydrogen peroxide and insoluble sodium metaphosphate (pH 5.5 of the paste) as a polishing agent. Teeth were polished for five minutes with a motor driven polishing brush. They found the average increase in enamel hardness to be +7.6 per cent. The authors conclusions were that the stannous fluoride prophylactic paste

in vitro does have an effect upon the enamel surface. This effect was less than the effect of similar concentrations of stannous fluoride in an aqueous solution.

Clinical studies also support the superiority of stannous fluoride over sodium fluoride. Howell, Gish, Smiley and Muhler¹⁸ conducted the first clinical study using stannous fluoride. A total of 1,200 children, ages 6 to 16 years, participated in the study. Group I received four applications of a 2.0 per cent aqueous sodium fluoride solution applied to all teeth with cotton applicator and permitted to air dry for four minutes. The second group received a 2.0 per cent aqueous stannous fluoride solution applied in the same manner as Group I. The third group received the 2.0 per cent stannous fluoride solution as spray, by such a technique that the teeth were maintained moist throughout the four minute application. The fourth group received only prophylaxis and served as controls. After two years, there was 36.3, 58.8 and 65.5 per cent less new decay (as expressed by the DMF surface index, respectively) when compared to the control. The results indicate a striking advantage for both stannous fluoride treatments over the sodium fluoride treatments.

McLaren and Brown¹⁹ conducted a two year clinical study comparing a 2.0 per cent sodium fluoride solution and a 2.0 per cent stannous fluoride solution, using the whole mouth technique. A series of four topical applications were given. For the first and second re-examination the number of children (aged 6 to 11 years) was 483 and 405. At the end of the first year, they observed 38.6 per cent

reduction in new carious surfaces for the sodium fluoride group and 46.3 per cent reduction for the stannous fluoride group. The authors stated that "both stannous fluoride and sodium fluoride treatment significantly reduce the incidence of caries". The authors also stated that the adjusted mean surfaces provide evidence which suggests the superiority of stannous fluoride over sodium fluoride as a topical agent for the partial control of dental caries. Valid comparisons between the two agents were impossible after two years due to the large number of subjects lost during the study.

Nevitt, Witter and Brown²⁰ compared four applications of either a 2.0 per cent sodium fluoride solution or 2.0 per cent stannous fluoride. Two groups of children aged 9 to 14 years were used. A total of 298 children were included in the sodium fluoride group and 290 children in the stannous fluoride group. A half-mouth technique was used. In all cases one-half of the mouth received four applications of distilled water and served as a control. At the end of a 16 months study period the sodium fluoride treated half-mouth showed 39.5 per cent fewer newly carious teeth, and the stannous fluoride treated half-mouth showed 44.4 per cent fewer newly caries teeth when compared to the control half respectively. The authors stated "The findings relative to the comparative effectiveness of stannous fluoride and sodium fluoride were inconclusive".

There is serious objection to the evaluation of stannous fluoride by the half-mouth technique due to a transfer of stannous ions to the untreated teeth.

This is demonstrated by Buttner and Muhler³⁶ that after topical treatments of 4.0 per cent stannous fluoride solution or 2.0 per cent sodium fluoride solution to the mandibular teeth of rats. The untreated maxillary teeth were protected against acid solubility as were the treated mandibular teeth. Because of these findings the authors advised against the use of half-mouth technique when studying fluoride effectiveness in human clinical subjects. Also the authors stated this is especially true when stannous fluoride is used since the stannous fluoride has such a pronounced affinity for enamel.

Meckel and Francis³⁷ later showed in vivo and in clinical studies that the half-mouth experimental technic is not valid, due to the intraoral transfer of fluoride and tin to the untreated side. Also they showed that part of this intraoral transfer did not occur immediately but proceeded over a period of 5 to 30 minutes after the topical application.

Law, Jeffreys and Sheary²¹ compared four applications of either 2.0 per cent sodium fluoride solution or 2.0 per cent stannous fluoride solution and one application of 8.0 per cent stannous fluoride solution. Over 700 children aged 7 to 13 years old, using half-mouth technique were used. After a 12 month period the children receiving four applications of either 2.0 per cent sodium fluoride or 2.0 per cent stannous fluoride solutions showed a 35 and 33 per cent reduction in DMF teeth respectively; 35.3 and 30.3 per cent reduction in DMF surfaces respectively. The group receiving single application of 8.0 per cent stannous fluoride showed 16.8 and 24 per cent reduction in DMF teeth

and DMF surfaces, respectively. The authors stated that reduction in the caries rate with both 2.0 per cent sodium fluoride and stannous fluoride solutions was significant and essentially the same. One application of 8.0 per cent stannous fluoride was considerably less effective and the reduction was not statistically significant.

Mercer and Muhler²² compared single application of an 8.0 per cent stannous fluoride solution with a 2.0 per cent sodium fluoride solution and two applications of 8.0 per cent stannous fluoride solutions. The second application of 8.0 per cent stannous fluoride was applied after 48 hours. A total of 600 children participated in the study who were between the ages of 6 to 14 years. At the end of one year, the group receiving one application of sodium fluoride solution showed negative results. The group receiving single application of stannous fluoride showed a highly significant reduction; 50 and 51 per cent in terms of DMF teeth and DMF surfaces respectively. The group receiving two applications of 8.0 per cent stannous fluoride solution also showed a highly significant reduction, 53 per cent in terms of both DMF teeth and DMF surfaces. It appears that the second application of an 8.0 per cent stannous fluoride solution gave no better reduction in dental caries as compared to the effect of the single application.

Gish, Muhler and Howell²³ reported the results of five years study comparing the effectiveness of a single application of an 8.0 per cent stannous fluoride solution with four applications of a 2.0 per cent sodium fluoride solution when applied to the permanent teeth of school children. The data showed a superiority for the children

receiving stannous fluoride of 38, 32, 31, 28 and 35 per cent, respectively, through years one to five in terms of DMF surfaces, and 34, 39, 30, 26 and 30 per cent, respectively, through years one to five in terms of DMF teeth. These results suggest the effectiveness of single application technique of stannous fluoride solution.

The effect of topically applied stannous fluoride and sodium fluoride solutions on deciduous teeth was studied by McDonald and Muhler.²⁴ Three equal groups received either four applications of a 2.0 per cent sodium fluoride solution or a 4.0 per cent stannous fluoride solution, or a prophylaxis only. At the end of one year the group receiving four applications of 2.0 per cent sodium fluoride showed 21 per cent reduction in DMF teeth and 12 per cent reduction in DMF surfaces. The group receiving four applications of 4.0 per cent stannous fluoride showed 57.6 and 37.0 per cent reduction in terms of DMF teeth and DMF surfaces, respectively. The authors concluded that the stannous fluoride was significantly superior to sodium fluoride.

Taken collectively, these studies would suggest overwhelming evidence in support of clinical effectiveness of the stannous fluoride.

Stannous Fluoride Containing Prophylactic Paste

Bibby and his co-workers in 1946³¹ suggested the incorporation of sodium fluoride in prophylactic paste as a method for topical treatment which was more simple than topical application of sodium fluoride solution and could be applied by the hygienist in the routine way of providing an oral prophylaxis.

In 1959 Segreto, et al³⁸ suggested that the incorporation of

stannous fluoride into a dental prophylactic paste would have the potentiality of combining a caries preventive treatment with each polishing procedure. As a result, they formulated a stannous fluoride silex-silicone dental prophylactic paste. The paste was tested in vitro for its anticariogenic potentialities. The data indicated that the 40 per cent stannous fluoride silex-silicone prophylactic paste provided about a 95.5 per cent protection to acid decalcification when compared to control teeth treated with water, and 74 per cent as compared to five minutes topical application of a 10 per cent stannous fluoride solution. This increase in effectiveness is explained on the basis of simultaneous³⁹ action of silex as a cleaning agent and stannous fluoride as a topical agent. Also the possibility of saliva contaminating the field is thus eliminated due to the presence of silicone and liquid petrolatum as the liquid ingredients in the paste.

In 1960 Segreto, et al⁴⁰ determined patients taste acceptance, the pastes polishing properties, and the possible contraindications of the stannous fluoride silex-silicone prophylactic paste. The study group consisted of 412 male military patients at four U.S. Air Force bases. Scale was used for the estimation of the taste acceptance ranged from 0 to 10 points (good = 10, bad = 0). The teeth were cleaned by a hygienist, and the results indicated that the average taste acceptance estimated by the patient was 4.5. The hygienist estimation for patients reaction was 5.4. The average hygienist evaluation of polishing capabilities of the paste was 5.1 per cent.

The majority of cases showed mild papillary and marginal blanching of the gingiva. This disappeared within a few days without treatment. The author stated that "on the basis of these data it was concluded that taste is the major contraindication to routine clinical application."

Hester, et al⁴¹ reported the patient taste acceptance and abrasive characteristic of a modified prophylactic paste formula (in the original formula the flavoring agents used were concentrated oil of orange and oil of anise, while in the modified formula the flavoring agents used were oil of peppermint and oil of anise, other ingredients were the same) when used with 4 to 17 years age group. The group included 56 females and 42 males. The authors stated that the ultimate success or failure of the clinical trial depended on the application and rinsing techniques suggested by the dentist or oral hygienist. The pastes were applied with a soft rubber cut at a relatively low speed. The same scale for the estimation of patients taste acceptance was used as in the previous study.⁴⁰ The result of this study indicated that the average patient taste acceptance was 4.72, and the operator scoring value was 5.66. Abrasiveness of the paste was satisfactory, exhibiting an average operator rating of 6.65. They suggested that in patient having cases of moderate-to-severe gingivitis the paste should not be used until the condition is subsided.

Wolf in 1961⁴² evaluated in vitro the effectiveness of the stannous fluoride-silex-silicone prophylactic paste which was formulated by Segreto.³⁸ The experimental method selected was one

in which the surface area of enamel specimens could be measured. The result showed that in comparison to the water control, the protective action toward acid decalcification of both the stannous fluoride-silex-silicone prophylactic paste and topical stannous fluoride solution after one and four hours incubation period were significant. The stannous fluoride solution was significantly more effective in preventing phosphorus loss than the fluoride paste after both one and four hours incubation period.

He concluded that to have maximum benefit to prevent enamel demineralization both the stannous fluoride prophylactic paste and aqueous fluoride solution should be used. In those cases where an aqueous stannous fluoride solution is not utilized, the stannous fluoride prophylactic paste should be employed.

Shannon in 1962⁴³ studied the effect of a 20 per cent aqueous stannous fluoride prophylactic paste on enamel solubility also attempt to determine the aging effect of this paste. He also compared the effect on enamel solubility of the aqueous stannous fluoride prophylactic paste to that of paste prepared with non-aqueous diluent in vitro. The results showed that there was over a 90 per cent reduction in enamel solubility afforded by the aqueous stannous fluoride prophylactic paste. There was no loss of effectiveness when the paste was aged over an eight-week period. When liquid petrolatum, silicone and petrolatum in combination were substituted for water, there was no increase in effectiveness.

Shannon⁴⁴ studied the in vitro effectiveness of silex-silicone

prophylactic paste in which containing 2.0 per cent by weight stannous fluoride in the final mixture, as well as the aging of this paste (in this study the age intervals referred only to the age of the stannous fluoride solution since fresh mixtures of the solution with the abrasive were prepared at each testing interval). The results showed that there were 76.3, 75.9, 85.6, 84.2, 84.2, 81.6 per cent reduction in enamel solubility, respectively, with the aged solution at 1, 2, 4, 8 and 22 weeks intervals, respectively. This showed that storage did not effect the protective action of the stannous fluoride solution.

Another study was conducted by Shannon⁴⁵ comparing the effect on enamel solubility of stannous fluoride solution when used as a 10 per cent topical, and as a component of a prophylactic paste. The compatibility of this solution was tested with flour of pumice and silex in a prophylactic paste. The solution was tested when fresh and at 2, 4 and 8 week intervals in vitro. Also a fresh stock solution of stannous fluoride was added to flour of pumice and silex separately. The paste was aged after mixing. The average stannous fluoride content of the final paste was 7.0 per cent with pumice and 3.7 per cent with silex. Again, here they found there was no apparent deleterious effect of aging on any of the preparation tested. The results showed that with the 10 per cent stannous fluoride solution applied topically, the reduction in enamel solubility ranged from 68.3 to 78.8 per cent at various intervals. Silex prophylactic paste prepared from aging stock solution provided protection from 68.2 to 79.1 per cent. The

flour of pumice prophylactic paste aged as mixed was 71.6 to 82.8 per cent effective while a comparable silex prophylactic paste reduced enamel solubility by 67.9 to 76.9 per cent.

Mericle and Muhler⁴⁶ conducted an investigation with the Air Force prophylactic mixture³⁸ which contained a 40 per cent stannous fluoride. This study was conducted to determine whether different combinations of active ingredients could be found that would result in similar antisolubility effects but at the same time have lower concentrations of stannous fluoride. Various abrasives with or without stannous fluoride in prophylactic mixture were evaluated for enamel antisolubility effectiveness in vitro. The more promising combination were evaluated in vivo. The data showed that when aqueous stannous fluoride solution were used with prophylactic abrasive was more effective than when solid stannous fluoride was added to non-aqueous abrasive containing system. Besides lower concentration of stannous fluoride could be used and still maintain high degree of enamel solubility.

The greatest antisolubility effectiveness resulted when stannous fluoride was used in combination with a prophylactic paste, topical application and in a dentifrice.

Shannon⁴⁷ conducted a laboratory investigation in which both commercially available and laboratory prepared stannous fluoride prophylactic paste in different concentrations were evaluated and their ability to decrease enamel solubility in lactic acid were studied. The findings also support the idea that lower concentration

(8 to 10 per cent) of stannous fluoride is almost as effective in reducing enamel solubility as the higher concentration (20 to 40 per cent). The lower concentration of 8 to 10 per cent stannous fluoride reduced the enamel solubility by 60 to 80 per cent and the higher concentration of 20 to 40 per cent reduced enamel solubility up to 88 per cent.

Evaluation of Stannous Fluoride Prophylactic Paste in Clinical Studies

Gish, Howell and Muhler⁴⁸ compared the clinical results of a study in which approximately 500 children receiving either a 50 per cent stannous fluoride containing prophylactic paste treatment or treatment with prophylactic paste without stannous fluoride each six months during one year study period. They found at the end of both six month and one year study period, the experimental group showed significant reduction in dental caries when compared to the control group. At one year the experimental group showed 60 and 62 per cent significant reduction in terms of DMF teeth and DMF surfaces as compared to the control group. Because of the percentage of stannous fluoride in the paste, the study was discontinued due to the undesirable side effects.

Peterson and his co-workers⁴⁹ reported the results at the end of a two year period of a clinical study using 17.5 per cent stannous fluoride silex-silicone prophylactic paste (Air Force prophylactic paste) on approximately 750 children ages 10 to 13 years living in a non-fluoridated area. The sample was divided into four groups. Group I received the experimental prophylaxis once a year for two years. Group II received the experimental prophylaxis each six

months for two years. Group III received the experimental prophylaxis followed by 8.0 per cent topical stannous fluoride solution once a year for two years, and the fourth group received a non-fluoride containing prophylactic paste once a year for two years and served as a control. Treatments were given by a hygienist. All children received clinical and radiographic examination initially and at the beginning of second year and third year by the same examiner. At the end of two years study period, the Group I showed 34.2 and 27.9 per cent reduction in DMF surfaces and DMF teeth, respectively. The second group showed 41.9 and 35.1 per cent reduction in DMF surfaces and DMF teeth, respectively. The third group showed 32.2 and 29.3 per cent reduction in DMF surfaces and DMF teeth, respectively, in comparison to the control group. The reductions were all statistically significant. The difference in reduction in dental caries between once a year (first group) and twice a year (second group) stannous fluoride silice-silicone prophylaxis paste treatment was not statistically significant.

Gish and Muhler⁵⁰ studied the anticariogenic effectiveness of 8.9 per cent stannous fluoride prophylactic paste (8.9 SnF₂ + lava pumice). The study group included 160 children ages 6 to 15 years living in a non-fluoridated area. The treatment was given by a hygienist once every six months. These children showed at the end of six months a 33.7 and 32.6 per cent reduction in terms of DMF teeth and DMF surfaces, respectively, in comparison to a control group.

In 1964²⁶ Bixler and Muhler reported the results of a six month and one year study using a 8.9 per cent stannous fluoride prophylactic

paste (8.9 per cent stannous fluoride + lava pumice). The number of children participating in the study was 223, ages 5 to 18 years. All of the participants were from non-fluoridated areas. They received both clinical and radiographic examinations initially at six month, and 12 month intervals. The dental prophylaxis treatment was repeated at the same interval. At the end of six month period, examiner A found a 12.9 and 17.5 per cent reduction in terms of DMF teeth and DMF surfaces, respectively, when compared to the control group. The results were not statistically significant. Examiner B found a 38.7 and 40.2 per cent reduction in terms of DMF teeth and DMF surfaces, respectively, in comparison to the control group; these results are statistically significant ($p < 0.003$).

At the end of one year period, both examiners found a significant reduction in dental caries. The group examined by examiner A showed 30.6 and 34.6 per cent reduction in terms of DMF teeth and DMF surfaces, respectively. Examiner B found 38.8 and 34.2 per cent reduction in DMF teeth and DMF surfaces, respectively, in comparison to their control groups which received prophylactic paste without stannous fluoride at the same interval.

In 1966⁵¹ the same authors reported the results at the end of 24 and 36 months study period. At the end of 24 months when the findings of the two examiners were combined, there were 30.0 and 34.2 per cent reduction in terms of DMF teeth and DMF surfaces, respectively. At the end of 36 months, again when the findings of both examiners were combined, there was a 32.5 and 35.0 per cent

reduction in terms of both DMF teeth and DMF surfaces, respectively. The reductions in dental caries at the end of both 24 and 36 months study periods were significantly lower than the control.

Gish and Muhler²⁵ reported the results of using a 9.0 per cent stannous fluoride prophylaxis paste in a community having an optimal fluoride level in the water supply. A total of 250 children included in the study in which 215 and 206 children ranging in age between 4 and 14 years were available for re-examination at the end of 6 months and 12 months, respectively. Only children who were life-long residents of the city and who had been away from the city for more than 60 days were included in the study. All children received clinical, radiographic examinations, and prophylaxis treatment each six months. At the end of the 6 and 12 month study periods, the experimental group examined by examiner A showed 37.6, 46.6 and 29.3, 39.6 per cent reductions in terms of DMF teeth and DMF surfaces, respectively, in comparison to the control group which received a placebo prophylaxis treatment.

The experimental group examined by examiner B at the end of the 6 and 12 month period showed 56.2, 60.4 and 45.1, 41.7 per cent reduction in terms of DMF teeth and DMF surfaces, respectively, in comparison to the control group. The results of this study showed that an additional benefit can be obtained by using stannous fluoride treatment in a fluoridated area.

Anticariogenic Effectiveness of Stannous Fluoride Prophylactic Paste on Adults

Muhler and Bixler⁵² conducted a clinical study in which 50 per

cent stannous fluoride silex-silicone prophylaxis treatment was given each six months to adult patients aged 17 to 59 years who were residents of a non-fluoridated area. At the end of six months and one year the experimental group showed 24.5 and 36.6 per cent reduction in terms of DMF surfaces, respectively, in comparison to the control group.

In another study by Bixler and Muhler²⁸ 159 adults aged 17 to 36 years who resided in a non-fluoridated area received a 15 per cent stannous fluoride silex-silicone prophylaxis paste treatment each six months. At the end of 6 and 12 month period, this group showed 31.5, 27.2 and 41.0, 30.5 per cent reduction in terms of DMF teeth and DMF surfaces, respectively, in comparison to the control group.

Scola in 1966²⁷ reported the use of a stannous fluoride prophylactic paste on adults. A total of 157 subjects, ages 17 to 24 years, received a clinical and radiographic examination each six months and a 17.5 per cent stannous fluoride in a compatible lava pumice prophylaxis paste treatment initially and every 12 months. After a 6 and 12 month period those patients had 9, 11 and 12, 12 per cent reduction in terms of both DMF teeth and DMF surfaces, respectively, in comparison to the control group which received placebo prophylaxis treatment at the same intervals.

The Use of Zirconium Silicate As an Abrasive System in a Prophylactic Paste

Laboratory and clinical studies have been conducted at Indiana University School of Dentistry in order to formulate an abrasive for use as a constituent of a prophylactic paste which provides

maximum cleaning and polishing for dental enamel, but minimum damage to the tooth structure.

Stookey, Hudson and Muhler⁵³ evaluated the polishing properties of different types and particle sizes of zirconium silicate in vitro. The teeth (human extracted anterior maxillary teeth) were polished by means of a rubber cup at 5,000 rpm. The speed was held constant at 5,000 rpm by means of constant transformer and the teeth polished for 30 seconds. In order to express all measurements in terms of a recognized standard polishing agent, each series of tests included a treatment with dry calcium carbonate and all data were expressed relative to this agent. Dry calcium carbonate was used as a standard due to its high degree of reproducibility and its known polishing properties. The data showed that the degree of polish is a function of the length of application and the amount of particles with small diameter (0-10 microns). Also the powder-water ratio and method of preparation of zirconium silicate effects the degree of polishing. When zirconium silicate was compared to other abrasives (flour of pumice, lava pumice, calcium pyrophosphate, tin oxide, etc.), zirconium silicate provides a better polishing than the other abrasives.

Muhler, et al⁵⁴ tested the cleansing and polishing ability of zirconium silicate clinically. Zirconium silicate was compared in its ability to remove different common forms of tooth stain and pigmentations with flour of pumice and lava pumice. All abrasives used had the same powder-water ratio (7:1) and all tooth surfaces (maxillary incisor) were polished for exactly 30 seconds. The results

of the study showed that zirconium silicate is better than flour of pumice or lava pumice in removing all types of stains which were studied. Also zirconium silicate and other abrasives (flour of pumice, mixture of equal amounts of insoluble sodium metaphosphate and tricalcium phosphate, tin oxide, and levigated alumina) were evaluated for their ability to prevent reformation of pellicle following a thorough prophylaxis. Zirconium silicate was by far the most effective. Also zirconium silicate was compared with flour of pumice in evaluating the reformation of materia alba. With flour of pumice, after 2.5 hours, reformation of materia alba occurred. While with zirconium silicate 86.0 hours were needed for materia alba to reform.

The compatibility of zirconium silicate with stannous fluoride has been also studied. Shannon⁵⁵ studied the effectiveness of a zirconium silicate prophylaxis paste containing different amounts of stannous fluoride in protecting human dental enamel from acid decalcification. He also studied the compatibility of this system when the paste aged over a period of eight weeks. The results showed that the freshly prepared zirconium silicate - stannous fluoride prophylactic paste is highly effective in protecting enamel from acid decalcification and the effectiveness is directly proportional to the concentration of the stannous fluoride. The paste which was aged over a period of eight weeks did not maintain its protective action to that high degree as did the freshly prepared prophylactic paste.

The compatibility of zirconium silicate and other abrasives with

stannous fluoride were studied by Kelley, Stookey and Muhler⁵⁶ both in vitro and in vivo. The effectiveness of a new stannous fluoride-phosphate prophylactic paste was also studied by them. The data showed that zirconium silicate - stannous fluoride prophylactic paste (with different concentrations of SnF_2) in general provided more protection than the other three abrasives (flour of pumice, lava pumice and silex) when used as a constituent of prophylactic paste under the same conditions.

When different phosphate systems were added to the zirconium silicate - stannous fluoride prophylactic paste, and the mixture tested in vivo (enamel solubility in rat), the data showed that monobasic sodium dihydrogen phosphate was more effective than the other phosphate compounds. The data showed that the addition of monosodium dihydrogen phosphate increased the effectiveness by nearly 50 per cent as compared to the same paste containing only stannous fluoride. When the zirconium silicate - stannous fluoride phosphate prophylactic paste was tested either fresh or aged, the results showed that the degree of effectiveness is not lost as a function of time.

Collectively, the results of both laboratory and clinical studies suggest that zirconium silicate - stannous fluoride-sodium dihydrogen phosphate prophylactic paste is the preparation of choice for providing maximum cleaning and polishing to the oral hard tissue, beside its high degree of antisolubility effectiveness.

Fluoride Containing Dentifrices and Their Clinical Evaluation

(i) Sodium Fluoride Containing Dentifrice

Dentifrice as a vehicle for the topical application of fluoride salts have been studied for a long time due to their availability and convenience for use by all classes of people. In 1945 Bibby⁵⁷ suggested that the use of fluoride-containing dentifrice should produce an effect like topical application even if the mixtures had lower fluoride concentrations since the more frequent application of fluoride to the teeth would enhance their effectiveness. The results of a two year clinical study when sodium fluoride was used in concentration of 0.01 and 0.1 per cent in liquid dentifrice and the same concentration in paste form were reported. Both children ages 4 to 16 years and adults 18 to 23 years used the experimental dentifrice under supervision conditions. The results showed no evidence of a reduction in the activity of dental caries in any of the experimental groups. The author stated that the negative results of the adult group was not surprising since they are in keeping with the results of mouth wash studies. But they could not explain the negative results of its use by the children group. But he stated that this could be due to relative inefficiency of tooth brushing especially in the children group.

Shaner and Smith⁵⁸ studied the effect of the daily use of a sodium fluoride dentifrice on the daily count of oral acidogenic bacteria (particularly Lactobacilli). A total of 47 adults were divided into three groups. Group A was given a prophylaxis and the

experimental dentifrice which contained 0.5 per cent sodium fluoride. Group B (the control group) was treated similarly as Group A and were given identical dentifrice except that it was fluoride-free. Group C was issued experimental dentifrice but they were not given a prophylaxis treatment. Saliva samples were obtained from each patient for three successive days initially and after four weeks. The data showed that daily use of the sodium fluoride dentifrice produced a reduction in the acidogenic organisms.

McClendon and Foster in 1947⁵⁹ used powdered Tennessee brown rock phosphate (4.0 per cent fluoride) on 40 medical students and synthetic fluoroappetite powder (total fluoride content 0.25 per cent) on other 30 medical students, because the powdered Tennessee brown rock phosphate contained 3.77 per cent iron and the test was unpleasant to some students, synthetic fluoroappetite powder was used. The students brushed their teeth with the experimental dentifrice daily, and at the end of one year, the group using the rock phosphate powder developed 0.5 new cavities per student. The group receiving the synthetic fluoroappetite powder developed 0.57 new cavities per student, while the 80 students which served as a control group had developed 1.5 new cavities per student. This is about a 60 per cent reduction in dental caries.

Winkler and his co-workers in 1953⁶⁰ used a fluoride containing dentifrice which contain 0.15 per cent sodium fluoride, and a control dentifrice which is the same as the experimental dentifrice except it was fluoride-free. The children in both experimental and control

groups were between the ages of 11 to 15 years. Both clinical and radiographic examinations were carried on by the same examiner initially and at 18 months for all children. After 18 months, the dental caries increment were remarkably equal in both the experimental and control groups not only in the total surfaces but also for each kind of surface.

(ii) Stannous Fluoride Containing Dentifrice

A. Studies Utilizing Stannous Fluoride Dentifrice by Children in Non-Fluoride Areas

Muhler suggested⁶¹ the idea of using stannous fluoride as a constituent of dentifrice. He formulated the dentifrice and with his co-workers conducted many clinical studies in order to study its anticariogenic effect.

In 1954 Muhler, et al⁶² reported the results of the use of the first stannous fluoride dentifrice. Approximately 450 children in a non-fluoride area, between the ages of 6 to 15 years, were divided into two groups on the basis of estimated caries expectancy. Each child received a thorough prophylaxis, a full-mouth bite-wing radiographic examination, and a clinical examination, initially and after six months. The experimental group used a dentifrice which contained 0.4 per cent stannous fluoride (0.1 per cent fluorine). The control group used the same dentifrice as the experimental group in every respect except that it did not contain stannous fluoride. The children were asked to use the dentifrice in their usual way. At the end of the six month period, the experimental group had a 53 and 72 per cent significant reduction in terms of both DMF

teeth and DMF surfaces, respectively, in comparison to the control group. When the different surfaces in the experimental group were compared to the control group, there were 100, 70, and 26 per cent reduction in the proximal, buccal, lingual and occlusal surfaces, respectively. The authors stated that all of the reductions are highly significant except the reduction in occlusal surface.

At the end of one year the experimental group showed 50.6 per cent reduction in teeth which were non-carious at the time of initial examination and 49.3 per cent reduction in all new DMF surfaces.⁶³ These reductions are also highly significant. When previously carious teeth were evaluated, the stannous fluoride dentifrice had an even more protective effect than on previously carious-free teeth. There was 62.1 and 40.5 per cent reduction, respectively, in previously carious and previously caries-free surfaces.

Muhler, Radike, Nebergall and Day⁶⁴ conducted a study to compare the anticariogenic effect of stannous fluoride and sodium fluoride containing dentifrice. Three groups of children, ages 5 to 15 years, and residents of a non-fluoride area were provided with either a stannous fluoride containing dentifrice (containing 1000 ppm fluorine as SnF_2), a sodium fluoride dentifrice (containing 1000 ppm fluorine as NaF) or a control dentifrice (containing no fluoride of any kind). Each of the 646 children received initially and at six month intervals a thorough dental prophylaxis, full mouth bite-wing radiograph and clinical examination. No instructions were given to the children

in regard to their home brushing habits. At the end of the six months period the group receiving sodium fluoride showed 8.0 and 14.3 per cent insignificant reduction in terms of both DMF teeth and DMF surfaces, respectively. The stannous fluoride group showed 45.5 and 44.7 per cent significant reduction in terms of both DMF teeth and DMF surfaces, respectively. At the end of one year, the group receiving sodium fluoride dentifrice had 2.2 and 9.9 per cent reduction in terms of DMF teeth and DMF surfaces, respectively, in comparison to the control group. The results were statistically not significant. The group receiving stannous fluoride dentifrice showed 33.9, 36.0 per cent significant reduction in DMF teeth and DMF surfaces, respectively.

In 1957⁶⁵ Muhler investigated the compatiability of the polishing agent (dicalcium phosphate) with stannous fluoride when used as a constituent of a dentifrice. Three groups of children from non-fluoride area ranging in age from 6 to 15 years were included in the study. They received either non-fluoridated dentifrice with the dicalcium phosphate as the polishing agent, or dentifrice identical to the first but containing 0.4 per cent stannous fluoride, or a dentifrice with heat-treated dicalcium phosphate as the polishing agent and 0.2 per cent sodium fluoride plus sufficient stannous gluconate to provide a final tin concentration of 3,000 ug/Gm dentifrice. After six months and one year period of unsupervised use of the experimental dentifrice, children in the two groups using the stannous fluoride dentifrice with the dicalcium phosphate

as the polishing agent showed any significant reduction in dental caries. The author stated "not only is the fluoride compound of importance in determining the anticariogenic effectiveness of the fluoride dentifrice, but also the nature of the polishing agent deserves important consideration".

In 1958 Muhler⁶⁶ studied the effect of adding small amount of insoluble sodium metaphosphate (calcium sequestering agent) to the stannous fluoride calcium pyrophosphate dentifrice. Approximately 600 children, ages 6 to 15, received either the control dentifrice or the experimental dentifrice. At the end of six months the group receiving the experimental dentifrice had 28 and 22 per cent fewer DMF teeth and DMF surfaces, respectively, in comparison to the control group. At the end of one year, the experimental group had 25 and 23 per cent fewer DMF teeth and DMF surfaces, respectively, than the control group. Both the six month and one year results were statistically significant. The results showed that the addition of a small amount of a calcium sequestering agent did not improve the anticariogenic effectiveness of the dentifrice.

Jordan and Peterson⁶⁷ conducted an independent study of the anticariogenic effectiveness of the stannous fluoride dentifrice in a non-fluoride area. All children used the dentifrice under supervision. The 505 children received a thorough clinical and radiographic examination initially and at the end of one year. The experimental dentifrice was similar to the control dentifrice except it had 0.4 per cent stannous fluoride and 1.0 per cent stannous

pyrophosphate. The pH was 4.9, while the control dentifrice pH was 6.8. At the end of one year the group receiving the experimental dentifrice showed a 35.4 and 33.9 per cent significant reduction in DMF teeth and DMF surfaces in comparison to the control group.

The above study was continued for another year. The data at the end of the two years study period showed that there was 16 per cent fewer DMF teeth and 21 per cent fewer DMF surfaces in the group using the stannous fluoride dentifrice than in the control group.⁶⁸

The above study was then discontinued for one year.⁶⁹ The results at the end of the three years showed that the effect of stannous fluoride dentifrice lasts not only while it is being used, but has also anticariogenic properties carried on after its discontinuation.

Peffley and Muhler⁷⁰ measured the effectiveness of the stannous fluoride dentifrice when used three times a day under supervision. A total of 318 children ages 10 to 19 years received either the stannous fluoride - stannous pyrophosphate dentifrice or identical dentifrice minus the stannous fluoride and stannous pyrophosphate. All children received a thorough clinical and radiographic examination initially and at 5, 10, 22 months after the start of the test. At the end of the five months period the results showed a highly significant reduction equal to 103 and 58 per cent in DMF teeth and DMF surfaces, respectively. At the end of 10 months there was 93 and 57 per cent reduction in DMF teeth and DMF surfaces, respectively. The authors concluded that the DMFS index offers a more complete and accurate representation of test results than does the DMFT index. Also they stated that the greater

effectiveness of stannous fluoride-calcium pyrophosphate dentifrice is associated with a more frequent use of the dentifrice.

Muhler⁷¹ evaluated the effect of a combination of topical application of stannous fluoride followed by the daily use of stannous fluoride dentifrice. A total of 751 children ages 6 to 15 years received either a single topical application of distilled water and a non-fluoridated dentifrice (Group A), or single topical application of distilled water plus a stannous fluoride dentifrice (Group B), or both a single topical application of an 8.0 per cent stannous fluoride solution and in addition the stannous fluoride dentifrice (Group C). All children were asked to use the dentifrice in their own usual way. The children received initially, at 6 month and 12 month intervals, a thorough clinical and radiographic examination, prophylaxis, and topical applications. At the end of six months Group B showed 38 and 32 per cent reduction in DMF teeth and DMF surfaces, respectively. The same group at the end of the 12 month period had 32 and 23 per cent reduction in DMF teeth and DMF surfaces, respectively. Group C at the end of six months had a 61 and 65 per cent reduction in DMF teeth and DMF surfaces, respectively. At the end of 12 month period the same group had 58 per cent reduction in both DMF teeth and DMF surfaces. The reductions in both groups (B and C) were statistically significant in comparison to the control group (Group A). This showed that the combination technique of using the single topical application of stannous fluoride and daily use of stannous fluoride dentifrice gives higher anticariogenic

effect than the stannous fluoride dentifrice alone.

At the end of two years the combined anticariogenic effect of a single topical application of stannous fluoride solution and daily unsupervised use of stannous fluoride dentifrice was reported.⁷² Children in Group B which received single topical application of distilled water plus a stannous fluoride dentifrice showed 33 and 25 per cent reduction in DMF teeth and DMF surfaces respectively. Children in Group C which received single topical application of 8.0 per cent stannous fluoride solution and in addition the stannous fluoride dentifrice showed 58 and 55 per cent reduction in both DMF teeth and DMF surfaces respectively. Muhler stated that there was no decrease in the results of both groups (B and C) as a function of time.

In another study, Muhler reported⁷³ the results of a three year clinical study using a combination of single topical application of stannous fluoride solution and daily use of stannous fluoride dentifrice. A total of 509 children ages 6 to 15 years, received a thorough clinical and radiographic examination and prophylaxis treatment initially and at six month intervals. Also the children received either topical application of distilled water and a non-fluoride containing dentifrice, or a single topical application of an 8.0 per cent solution of stannous fluoride and the stannous fluoride dentifrice for daily use at home. The experimental group at six months showed a 60 and 65 per cent reduction in DMF teeth and DMF surfaces, respectively. At 12 months they showed a 58 per

cent reduction in both terms DMF teeth and DMF surfaces. In 18 months the values were 59 and 56 per cent, and at 24 months they were 58 and 55 per cent. After 36 months a 57 and 63 per cent reduction in DMF teeth and DMF surfaces, respectively, were found in comparison to the control group. The reductions were highly significant at the end of each study period, and the results showed that in non-fluoride area the use of more than one effective anti-cariogenic agent produce cumulative effects. These data strongly suggest the use of "Multiple Principles of Preventive Dentistry".

Muhler⁷⁴ conducted a three year study in order to evaluate the clinical effectiveness of the stannous fluoride-calcium pyrophosphate dentifrice. A total of 492 children were included in the study ranging in ages 6 to 18 years. All children used the dentifrice according to their normal brushing habit pattern. At the six months re-examination period, the experimental group showed a 41 and 26 per cent reduction in dental caries, at 12 months a 32 and 24 per cent reduction, at 18 months a 36 and 28 per cent reduction, at 24 months a 28 and 24 per cent reduction, and at 36 months a 22 and 21 per cent reduction in terms of both DMF teeth and DMF surfaces, respectively. The reductions were significant at each re-examination period.

Zacherl, et al⁷⁵ tested the effectiveness of the stannous fluoride-calcium pyrophosphate dentifrice in two specific age groups (children of grade 1, 2 and 7). The number of children included in the study was 1,713. All children received initially and after 10 and 18 months, clinical and radiographic examination. At the end of 10 months

children in grade 1 and 2 (Group 1) had 36.3 and 39.2 per cent reduction in DMF teeth and DMF surfaces increment, respectively. At 18 months they showed 34.4 and 42.1 per cent reductions in teeth and surfaces increment, respectively. Children in grade 7 (Group 2) at 10 months had 22.7 and 34.1 per cent reductions, and at 18 months 34.8 and 38.7 per cent reductions, in teeth and surfaces, respectively, in comparison to the control group. The authors conclusions were: "This study indicates that the effect of stannous fluoride-calcium pyrophosphate dentifrice is not dependent upon age of the subjects. The effect exhibited appears to be proportional to the magnitude of the caries problem rather than being a constant effect independent of the caries problem".

Torell⁷⁶ studied the effect of stannous fluoride-calcium pyrophosphate dentifrice in comparison to the control dentifrice (the same formulation without fluorine) on a number of participants who were 10 years old. The caries rate of 169 children in the experimental group, and 179 children in the control group were calculated. At the end of a two year study period, the clinical examination results showed 23 per cent reduction in DMF surfaces, and radiographic examination showed 12 per cent reduction in DMF surfaces in the experimental group over the control group.

Horowitz, et al⁷⁷ conducted a three year study in order to determine the efficacy of the stannous fluoride-calcium pyrophosphate. Three groups of children in grades 1 through 3 were included in the study. One of the three groups was divided into two sub-groups, one

brushed with the experimental dentifrice at home (Group 1), the other sub-group brushed in the same manner with placebo dentifrice (control). The second group was also divided into sub-groups, one brushed with the experimental dentifrice at school once a day as well as at home (Group 2), the other group brushed in the same manner with the placebo dentifrice (control). The third group brushed at home with the dentifrice of their choice. After one year re-examination, Group 1 showed 11.3 and 8.3 per cent insignificant reduction, at two years period 11.8 and 5.2 per cent insignificant reduction and at three years period 17.0 and 17.2 per cent significant reductions in DMF teeth and DMF surfaces, respectively, in comparison to the control group brushed in the same manner. Group 2 after one year had 10.3 and 10.8 per cent insignificant reductions, at the two year period had 17.1 and 14.9 per cent significant reductions, and at the three year period had 17.0 and 20.7 per cent significant reductions in DMF teeth and DMF surfaces, respectively, in comparison to the control group brushing with the placebo dentifrice in the same manner. The results were not compared to Group 3 because of the various commercial dentifrices used by this group. The results showed, as the study progressed, there was a trend, in both Group 1 and Group 2 toward an increased reduction of dental caries. Brushing once a day at school as well as at home resulted in no additional benefits for caries control compared with benefits gained by children who brushed their teeth only at home with the same dentifrice.

Thomas and Jamison⁷⁸ studied the effectiveness of two different stannous fluoride containing dentifrices, one with insoluble sodium metaphosphate as a compatible polishing agent used by Group 1, and the other with calcium pyrophosphate as the compatible polishing agent used by Group 2. All of the 679 children (ages 7 to 16) in the study and control groups used the dentifrice twice a day under supervision. At the end of a two year study period both Group 1 and Group 2 showed approximately the same reduction in DMF surfaces and 37.1 per cent for Group 1 and 35.7 per cent for Group 2 in comparison to the control group.

Halikis⁷⁹ studied the effectiveness of a commercially available stannous fluoride dentifrice which contains 0.4 per cent stannous fluoride and 1.0 per cent stannous pyrophosphate. A total of 53 boys between the ages of 9 and 14 years used the stannous fluoride dentifrice. A total of 53 boys the same age used an identical dentifrice but not containing stannous fluoride or stannous pyrophosphate. All children at the beginning of the study were given lectures on the advantages of toothbrushing and shown how to brush their teeth. Over a period of 15 months, the stannous fluoride group showed 25.2 and 27.3 per cent reduction in terms of both DMF teeth and DMF surfaces, respectively.

All the above studies on children showed significant caries reduction with the use of the stannous fluoride containing dentifrice. But the following studies showed either insignificant or negative reductions with the use of stannous fluoride containing dentifrice.

In some of these studies, the abrasive and other components of the dentifrice were different from that used in the previous studies. It had been shown⁶² that the polishing agent deserves important consideration in determining the anticariogenic effectiveness of the fluoride dentifrice.

Hill⁸⁰ studied the effect of stannous fluoride dentifrice on children ranging in ages from 9 to 16 years. The children in both control (190 children) and experimental group (189 children) were given a prophylaxis twice a year by a hygienist who gave repeated instructions on home care. The dentifrice was used at home under unsupervised conditions. At the end of one year the experimental group had 16 and 14 per cent reductions, and the second year 12 and 15 per cent reductions in DMF teeth and DMF surfaces, respectively, over the control group. The author stated "Although these figures are not statistically significant, there was a small reduction in caries noted at each of the four examinations during the two year period".

Finn in 1963⁸¹ reported the results with the use of stannous fluoride dentifrice in comparison to other therapeutic dentifrices. A total of 428 children with average age 11.42, 11.60 and 11.74 years, respectively, received a thorough clinical and radiographic examination initially and at six month intervals during a two year study period. Children received either a sodium monofluorophosphate dentifrice - Group 1 (formulated in a compatible base of insoluble sodium metaphosphate as the polishing agent) or 0.4 per cent stannous

stannous fluoride dentifrice - Group 2 (compatible base with calcium pyrophosphate) or sodium N-Lauroyl sarcosinate - Group 3 (compatible base with dicalcium phosphate dihydrate). All children were given toothbrushing instructions with emphasis on brushing after every meal under supervision. At the end of a two year study period, children in Group 1 had 24.9 and 26.4 per cent fewer DF teeth and DF surfaces than in Group 2, respectively, which were highly significant, and 15.6, 18.7 per cent fewer new DF teeth and DF surfaces than in Group 3, respectively, which were insignificant. Group 3 had 11.1 and 9.5 per cent fewer new DF teeth and DF surfaces than Group 2 which were not significant.

The author stated "This study does not imply that either the stannous fluoride or sarcosinate dentifrice will not produce a reduction in dental caries; they may well do so. However, if a reduction is achieved it is similar in both the stannous fluoride and sarcosinate dentifrices with significantly less caries inhibition than found for the sodium monofluorophosphate dentifrice tested".

Slack and Martin in 1964⁸² reported on the results of a study involving approximately 700 children, ages 11 to 13, using either an experimental or control dentifrice. The experimental dentifrice contained 0.4 per cent stannous fluoride in a compatible base formula containing insoluble metaphosphate. All children received toothbrushing instructions with emphasis on brushing after each meal. After two years, the results showed no difference in the rate of dental caries between the study and the control groups.

The authors stated that the results were surprising in comparison with the majority of reports published on the efficacy of a dentifrice containing stannous fluoride in the control of dental caries. Further, it is unlikely that the placebo dentifrice used by the control group had any anticariogenic effect.

Brudevold, Chilton and Wellock⁸³ tested five different dentifrices under unsupervised toothbrushing conditions.

- (i) Commercially available anti-carious dentifrice containing stannous fluoride (Group 1).
- (ii) Commercially available fluoride-free dentifrice (Group 2 - control).
- (iii) Sodium fluoride, acid orthophosphate, calcium-free abrasive system (Group 3).
- (iv) Stannous fluoride calcium-free abrasive system (Group 4).
- (v) Commercially available dentifrice containing sodium fluoride and secondary calcium phosphate (Group 5).

A total of 2,150 children ages between 11 to 19 years were included in the study. At the end of the first year the data indicated that children in Group 1 which used the commercially available stannous fluoride dentifrice showed 1.7 and 9.9 per cent reduction in DMFT and DMFS, respectively, as compared to children in the Group 2 (control) which used commercially available fluoride-free dentifrice. Children in Group 3 which used sodium fluoride, acid orthophosphate, calcium-free abrasive system showed 8.8 and 17.5 per cent reduction in DFMT and DMFS, respectively, as

compared to the control. Children in Group 4 which received the stannous fluoride calcium-free abrasive system showed 13.0 and 18.4 per cent reduction in DMFT and DMFS, respectively, as compared to the controls.

The author stated that only children in Group 3 which received the sodium fluoride, acid orthophosphate, calcium-free abrasive dentifrice showed significant reductions in dental caries when compared to the controls and to children in Group 1 which received the commercially available stannous fluoride dentifrice.

B. Clinical Studies Utilizing Stannous Fluoride Dentifrice by Children in Fluoride Areas

Muhler, Gish and Stookey⁸⁴ studied the effectiveness of a stannous fluoride-calcium pyrophosphate dentifrice in reducing dental caries in a fluoride area. Approximately 500 children, 6 to 14 years of age, were divided into two groups. Group 1 used the commercially available SnF_2 stannous pyrophosphate dentifrice. Group 2 used identical dentifrice minus the stannous fluoride and stannous pyrophosphate. Two examiners participated in the study. Each examined one-half of all children. The children received a thorough clinical and radiographic examination initially, at six months and 12 months interval. At the end of six months, the children examined by examiner A had 36.5 and 54.7 per cent reductions, at one year 15.8 and 38.3 per cent reductions in DMF teeth and DMF surfaces, respectively, in comparison to the control group. Children examined by examiner B at the six month period had 34.8 and 42.5 per cent reduction, at one year had 28.6 and 31.1 per cent reductions

in DMF teeth and DMF surfaces, respectively, in comparison to the control group. The reductions in dental caries were statistically significant. The use of stannous fluoride calcium pyrophosphate dentifrice in the fluoride area appear to add to the benefit derived from the systemic ingestion of fluoride from a communal water supply.

In 1966⁸⁵ the above authors reported the results at the end of the two year study period. The children examined by examiner A had 23.1 and 35.4 per cent significant reduction in DMF teeth and DMF surfaces, respectively. The children examined by examiner B had 25.7 and 29.5 per cent significant reductions in DMF teeth and DMF surfaces, respectively, in comparison to the control. This result showed that the effect of the stannous fluoride containing dentifrice is not decreased significantly as a function of time.

C. Clinical Studies Utilizing Stannous Fluoride Dentifrice by Adults in Non-Fluoride Areas

Muhler, et al in 1956⁸⁶ conducted a study in which the effectiveness of stannous fluoride dentifrice used by adults ages 17 to 36 was evaluated. Two groups received dentifrices, the composition of which were identical except that one contained approximately 1 mg. fluoride and 3 mg. tin per gram of dentifrice. The patients received a dental prophylaxis, thorough clinical examination with the aid of complete bite-wing radiographs, initially, and at six month intervals. All students used the dentifrice according to their individual brushing habits. At the end of six months, the group receiving the stannous fluoride dentifrice had 55.0 and 50.4 per cent significant reductions

in dental caries in terms of DMF teeth and DMF surfaces, respectively. At the end of one year, the same group had 53.7 and 41.6 per cent significant reduction in DMF teeth and DMF surfaces, respectively.

The previous⁸⁶ study was continued for another year.⁸⁷ The patients in the second year received dental prophylaxis, clinical and radiographic examination at the end of the 24 months study period only. The results at the end of the two year period showed that the reduction in dental caries rate in terms of DMF teeth was 30 per cent and a statistically significant reduction of 34 per cent in terms of DMF surfaces. The authors concluded that "although this result is not greatly different from that obtained at the end of first year (41.6 per cent reduction in DMF surfaces), there is a possibility that the dentifrice decreased in effectiveness on prolonged storage".

Kyes, Overton, and McKean⁸⁸ conducted a clinical study for a two year period on adults. The purpose of the study was to compare the anticariogenic effectiveness of stannous fluoride and sodium fluoride (plus N-lauroyl sarcocinate) containing dentifrice. The dentifrices were used by adults ages 17 to 24 years old, under unsupervised conditions. At the end of one year, the stannous fluoride group showed 0.5 per cent reduction in DMF surfaces and 14 per cent reduction at the end of the second year compared with the control group using non-medicated dentifrice. The sodium fluoride-sarconcinatate group showed 19 per cent increase in DMF surfaces the first year and 2.0 per cent reductions in the second

year as compared to the control group. None of the reductions or increase were statistically significant.

D. Other Fluoride Containing Dentifrice Utilized for Their Effectiveness on Dental Caries

Marthaler⁸⁹ studied the effectiveness of an amine dentifrice on dental caries in the permanent teeth of children over a period of three years. A total of 589 children ages 6 to 9 divided into four groups were included in the study. Another 370 children ages 11 to 14 were also included in the study and divided into four groups also. All children received a clinical and radiographic examination initially, at 6 months, 18 months, and 3 years after the initial examination, respectively. All the groups of children (ages 6 to 9 and 11 to 14) received the following dentifrices:

(i) First group received dentifrice containing two amine fluoride compounds with insoluble metaphosphate (IMP) (experimental). (ii) Second group received dentifrice identical to the amine fluoride dentifrice minus the fluoride compound (control). (iii) Third group received dentifrice containing two amine fluoride compounds with barium sulphate instead of (IMP) (experimental). (iv) Fourth group received identical dentifrice as the third group minus the fluoride compound (controls). The children in all groups used the dentifrice under unsupervised conditions. The data showed that the groups of children ages 6 to 9 had 0.0, 43.0 and 30.0 per cent reductions in DMF surfaces in the intervals 0 to 6 months, 7 to 18 months, and 19 to 36 months, respectively, as compared to the control group. The findings of the children ages 11 to 14 were 10.0, 36.0 and

23.0 per cent reductions in DMF surfaces, respectively, in the same period as the younger group in comparison to the control group. In conclusion the author says "The lack of effectiveness during the initial period followed by a period of substantial caries inhibition disagrees with the findings reported in most clinical trials with stannous fluoride dentifrices. The inhibition in the third study period was 13 per cent lower than in the second. This may be due to loss in effectiveness, to the interruption in the use of the dentifrices, or to mere chance".

A fluoride containing dentifrice (Cue)⁹⁰ was evaluated for its effectiveness on dental caries. The active ingredient in the product is 0.4 per cent stannous fluoride, with insoluble sodium metaphosphate as the polishing agent. Three clinical studies were conducted in children ages 5 to 16 years, each of which were of two years duration. In one study brushing was supervised three times a day. The second study was conducted in an area with optimal fluoride level in water supply. In the third study brushing was unsupervised. The results showed 37.0, 16.0 and 17.0 per cent reductions in DMF surfaces, respectively, in all the three studies when compared to the control groups.

Another fluoride containing dentifrice⁹¹ (Super Stripe) was evaluated for its anticariogenic effect. The active ingredients is 0.4 per cent stannous fluoride with insoluble sodium metaphosphate and calcium pyrophosphate. A clinical study of two years duration was conducted on a group of school children ranging

in age from 7 to 12 years. Both the experimental and control groups used the dentifrice under supervised class room brushing once a day during the school year. The two years data indicate a 19.0 per cent significant reduction in DMF surfaces as compared with the placebo dentifrice.

Both the above dentifrices (Cue and Super Stripe) are classified by the American Dental Association, Council on Dental Therapeutics in grade B.

Tooth Brushing With Dentifrice as a Substitute for Prophylaxis Before Topical Application of Fluoride Solutions

Chritzberg, in 1951,⁹² wrote that for the partial control of dental caries the topical application of 2.0 per cent sodium fluoride solution to the teeth of children had become a generally accepted preventive measure. The topical application should be preceded by cleaning the teeth with a prophylactic paste by the dentist or dental hygienist. However, in a public health preventive program, the benefit of topical application could be provided to a large group of children, but the preceded recommended prophylaxis which requires finances and time places limitation on the project. As a result, he tested the hypothesis of whether or not brushing the teeth for two weeks under the supervision of a classroom teacher could be substituted for the prophylaxis recommended before the first topical application of sodium fluoride solution without decreasing the effectiveness of the treatment. The study was initiated with three groups, including 234, 230, 286 children between the ages of 6 to 12 years. Children in Group 1 were given

small toothbrushes and tooth powder that had no known caries inhibiting effect. In the dental health education given to the children, the rotary method of brushing the teeth was taught. Teachers were instructed to supervise the children in the classroom for toothbrushing twice daily, in the morning and after lunch period. At the end of two weeks brushing period, children received the initial clinical examination which was followed by the first topical application of 2.0 per cent sodium fluoride in the usual way by the dentist or hygienist. Second, third and fourth applications were given at weekly or semi-weekly interval. The children continued to brush their teeth under supervision until they received the fourth application. Then the children were asked to continue brushing at home after the fourth application. Children in Group 2 received initial examination and were given dental prophylaxis and topical application of 2.0 per cent sodium fluoride solution by the dentist or dental hygienist in the usual way. Children in Group 3 (control) received only an initial examination and were provided with toothbrushes to brush their teeth at home without any instruction given to them. After one year re-examination, Group 1 showed 47.0 per cent reduction in DMF teeth, and Group 2 showed 45.0 per cent reduction in DMF teeth, as compared to the control. The author concluded that "This modification of technic should aid materially in increasing the number of children treated, because the time which is generally required to give the cleansing can be utilized for applying the solution". Also he stated that

further studies may show that one thorough brushing immediately before the application of sodium fluoride may provide the same results.

The same type of clinical study was conducted where single topical application of 8.0 per cent stannous fluoride was given by the dentist or hygienist after two weeks of supervised brushing with neutral dentifrice twice daily.⁹³ A total of 628 children ages 6 to 12 years were divided into two groups. Group 1 received single topical application of an 8.0 per cent stannous fluoride solution for two minutes (the teeth kept moist during the two minute application period). Group 2 received topical application of tap water. The children, before receiving the topical applications were taught a toothbrushing method in which they brush the smooth surfaces with slightly rolling, circular motion and rotary scrubbing motion to clean the occlusal surfaces. After one year re-examination, Group I showed a 30.0 and 21.0 per cent significant reduction in DMF teeth and DMF surfaces in comparison to the control group. This result showed that the modified technique of cleaning the teeth could be used with both sodium and stannous fluoride solutions without decrease in effectiveness.

Self-Application of Concentrated Fluoride Solution by Toothbrushing

In 1953-1956⁹⁴ a supervised toothbrushing pilot study with 0.5 per cent sodium fluoride solution in an elementary school was performed by Berggren, et al. A reduction of 25.0 per cent in the number of teeth requiring restorative treatment was noted. Another study was conducted by Berggren, et al in 1957⁹⁴ using 1.0 per cent

sodium fluoride solution on larger scale of children from non-fluoridated area. The experimental group included 5,000 children ranging in age from 7 to 13 years. Each child was supplied with about 30 ml. of a 1.0 per cent sodium fluoride solution in parchment beakers, into which the toothbrushes were dipped. The children brushed their teeth carefully under supervised conditions for about four minutes according to the usual method. In the first and second grades, only two children were given instructions at a time (in this age group brushing for the most part was performed by the dentist and the chairside assistant). In older grades, the number of children increased to a maximum of five or six (in this age group they performed the brushing themselves without help). During the first year study period the children received five applications and during the second year four applications of sodium fluoride. The control group included 10,000 children in other schools which received only clinical examination. A total of 568 children from the study group, and 1,116 children from the control group were selected for dental caries recording in consultation with the statistical institute. Only one quadrant was recorded in each child according to the so-called rotation system. The magnitude of the dental caries inhibiting effect was calculated on the results of the sodium fluoride application on the maxillary teeth.

The conclusions of the authors were: There was a definite inhibition of caries on the teeth erupted during the study period; the maxillary teeth showed a greater reduction in dental caries

than the mandibular teeth; this could have resulted from the fact that the maxillary teeth are brushed more carefully than the mandibular teeth. Also, the abundant supply of saliva around the mandibular teeth could have diluted the fluoride solution.

- The mean reduction in dental caries calculated for the maxillary teeth was 25.0 to 30.0 per cent when compared with the control group.

- Up to 200 children per day could be treated using this method.

- The simplified time saving method that permits treatment of the greatest number of children is certainly to be preferred even if the percentage of effectiveness is somewhat reduced.

Berggren and Welanders⁹⁵ conducted another clinical study in which the annual number of sodium fluoride application was varied from that utilized in their previous study.⁹⁴ Beside sodium fluoride solution, other fluoride compounds as ferric fluoride and zirconium fluoride were tested on the same basis. Approximately 1,300 children at 10 elementary schools who were 10 years old were included in the study. The dental caries inhibiting effect of the three different fluoride solutions were tested by brushing techniques performed either twice or five times per year. The same procedure of brushing and dental caries diagnosis was used as described in the previous study.⁹⁴ The data from this later study showed that during the two year study period, the dental caries reduction for the whole dentition was 29.0 per cent when five annual brushing with sodium fluoride solution was performed. The group which performed five annual brushing with zirconium fluoride solution showed 17.0 per

cent reduction in dental caries, and the group using ferric fluoride solution also five annual brushing showed 33.0 per cent reduction in dental caries.

For the two annual brushings of the three fluorides group, the caries reductions were 17.0, 0.0 and 8.0 per cent, respectively. The five annual brushings had a better effect on dental caries reduction, irrespective of which fluoride compound was used than the two annual brushings. The two annual brushings had only a small difference between the test and the control groups. In comparing the three different fluoride compounds, the five annual brushings with sodium fluoride and ferric fluoride were highly significant and superior to zirconium fluoride.

A study was conducted on school children in Modum (Norway) for three years to evaluate the effectiveness of self-application of a 1.0 per cent sodium fluoride solution by means of toothbrush.⁹⁶ Approximately 800 children ages 7 to 14 were treated every year. The children brushed their teeth in the school four times a year under supervision of the teacher. The results were evaluated by comparing the number of restorations performed during a one year period before the start of the study with these performed in the one year period after the three year study period. These data showed a reduction of 42.6 per cent in the number of new restored surfaces. The author stated: Since only the number of new restorations had been counted, the figures do not strictly reflect the incidence of caries but the number of restored surfaces.

O'Hickey⁹⁷ described the self-application procedure which was followed by school children in Ireland in applying 1.0 per cent sodium fluoride solution to the teeth by means of toothbrush. A group of about 12 children at a time were given a demonstration by the supervising dentist on the correct way of toothbrushing. The children then cleaned their teeth with prophylactic paste by means of the toothbrush. After thorough cleaning and rinsing, the children were supplied with the fluoride solution and allowed to brush for four minutes. The younger children were sometimes helped by the supervising dentist in brushing their teeth. No clinical results were reported.

Rosenkranz, et al⁹⁸ reported that the self-application by means of toothbrush of a solution containing soluble zirconium citrate-fluoride complex was tested for its effectiveness on dental caries. The teeth of experimental subjects were brushed six times a year. After one year the experimental group had a mean number of new DMF surfaces equal 4.24 ± 0.54 , while the control group had 6.47 ± 0.67 . This represents a reduction of 34.0 per cent in DMF surfaces in the experimental group.

Goaz, et al⁹⁹ studied the effect on the dental caries of 6.0 per cent sodium monofluorophosphate when applied to the teeth with a toothbrush in a fluoridated area. Children in grades 1 through 7, ages 6 to 14 years, were divided into two groups. All children received a clinical and radiographic examination of their posterior teeth initially, at 9 and 14 month intervals, by the same examiner.

Group I, which included 110 subjects, were supplied with a pink, flavored solution containing a 6.0 per cent sodium monofluorophosphate solution, Group II, which included 109 subjects, was supplied with the same solution, but with sodium chloride substituted for the fluoride compound. The solutions were supplied in small plastic bottles. All children were asked to brush their teeth once daily with the above solutions, by following their usual brushing habits, but not to use a fluoride containing dentifrice or have a topical fluoride treatment during the study period. The data at the end of the 9 and 14 month intervals included both deciduous and permanent teeth. The experimental group at 9 months had a 30.9 per cent lower R.I.D. (the R.I.D. index is the ratio of the number of surfaces becoming carious or restored during a given interval, to the total number of surfaces at risk during that interval) in comparison to the control group. Also the same group showed a 25.5 per cent reduction in DFS (number of new decay and filled surfaces) in comparison to the control. At the 14 month interval the R.I.D. was 39.4 per cent lower than the control and 42.1 per cent lower DFS index than the control group. Also the data showed the experimental group had 41.0 and 66.0 per cent more reversals (or remineralized lesions) after 9 and 14 months interval than those in the control group. These results indicate a significant additive anticariogenic effect of sodium monofluorophosphate to that occurring from water fluoridation.

The above study was continued for another seven months.¹⁰⁰

The data of the 170 participants completing the study (82 experimental, 88 control), showed that Group I which used the self-application of the 6.0 per cent sodium monofluorophosphate solution at the end of 21 months had a 51.5 per cent lower R.I.D. and a 52.3 per cent lower DFS than the control. The average number of reversals was 66.0 per cent in the experimental group as compared to the control group. On the basis of estimation of the regularity with which the test solutions were used, it was found that there was no correlation between the dental caries experience and the frequency with which the solutions were used. The use of sodium monofluorophosphate once or twice a week may be as effective in reducing the dental caries when it is applied daily.

Bullen and his co-workers¹⁰¹ studied the effect on dental caries of an acidulated fluoride-phosphate solution. Approximately 815 children, six years old, brushed their teeth with an experimental solution (acidulated fluoride-phosphate) or a control solution (distilled water) under supervision of the class teacher five times during the school year. All children received a clinical examination initially and at the end of one year. The results of the study were presented in terms of the solutions effect upon deciduous and permanent teeth (first permanent molars and lower incisors). After the one year re-examination period, there was no observable effect upon the caries increment of the deciduous dentition, while there was a 38.5 per cent reduction in DMF surfaces of the newly erupted first permanent molars and incisors in the experimental group as

compared to the control group. The authors conclusion that further study is necessary to ascertain whether this is a practical method of caries prevention.

The above study was continued for a second year¹⁰² at which time nine brushings had been completed during a two year school period. Re-examinations at the end of two years showed that the experimental group had 15.0 per cent fewer new DMF surfaces than the control group. The results after two years were less favorable than at the end of the first year. The absolute difference in caries increment between the two groups was not changed during the second year. This suggests that the experimental group derived no further benefit during the second year of the study.

Self-Application of Stannous Fluoride Prophylactic Paste

When stannous fluoride has been used by means of a multiple fluoride therapy technique, (prophylactic paste, topical application, and daily use of $\text{SnF}_2\text{-Ca}_2\text{P}_2\text{O}_7$ dentifrice) a 58.0 to 76.0 per cent caries reduction is obtained.²⁵⁻²⁷ The results of the three agents are known to produce cumulative effects. The stannous fluoride in a compatible prophylactic paste itself contributed a significant portion of the total cariostasis. The application of the prophylaxis alone requires approximately 15 to 25 minutes for each patient.

Foster¹⁰³ designed a study to evaluate the feasibility of self-prophylaxis with stannous fluoride prophylactic paste versus routine rubber-cup applied prophylaxis. In this study, the prophylaxis was limited to supragingival polishing of teeth with

an 8.9 per cent stannous fluoride in a compatible pumice paste. Men 17 to 23 years old were selected at random who were free from periodontal disease. A total of six to seven subjects at a time were instructed by a "dental technician"* on how to brush their teeth (modified Stillman/McCall method), after which they brushed for 10 minutes under supervision. The control subjects were given a prophylaxis by "dental technicians". The dental technicians were asked not to scale the teeth but only to perform the routine rubber-cup prophylaxis using the same paste. The time required for each prophylaxis was recorded. Erythrosine disclosing tablets were used by all subjects in order to stain the plaque before and after the prophylaxis.

Four groups comprising of 100 subjects were compared in the study. Group A used a hard-type nylon brush (two rows, and six tufts) for self-prophylaxis. Group B received a prophylaxis by the dental technician. Group C also received a prophylaxis by the same technicians after Group B. There is no difference between Group B and C. The reason given by the author that another group is used to receive the prophylaxis paste by means of the routine rubber-cup procedure was to evaluate if the dental technician will improve their experience in cleaning the teeth after they completed the first group, and also to evaluate the fatigue ability of the dental technician to perform the cleaning procedure later in the day. Group D used hard natural bristle brushes (three rows and six tufts)

* The author did not explain what he meant by the term "dental technician".

for self-prophylaxis. (The difference between this group and Group A is only in the type of tooth brush used).

The comparison between the four groups showed that those in Group A in which the average time for brushing was 10 minutes, removed 71.1 per cent of the plaque. Group B subjects required 13 minutes, with 73.8 per cent average plaque removal. Group C subjects needed 12 minutes and the plaque removal was 74.8 per cent. Group D subjects average 9.9 minutes brushing time, and the average plaque removal was 70.4 per cent. From the above results one can conclude that self-prophylaxis is as efficient as a prophylaxis performed by a technician.

Several clinical studies were conducted by the U.S. Navy¹⁰⁴ in which the idea of self-prophylaxis was studied. The procedure described by Kyes using a group of 10 subjects (ages 17 to 24 years) under the supervision of one dental technician brushed their teeth for 10 minutes with a 17.5 per cent stannous fluoride prophylactic paste. Then the patients received topical application of 10.0 per cent stannous fluoride solution and daily use of stannous fluoride dentifrice. Results of these studies are not yet available.

Self-Application of Fluoride Containing Mouth Washes

The concept of using mouth wash containing fluoride is not new, but little work has been published concerning this subject. Bibby, et al³¹ reported the first clinical study in this area. In their study a 0.1 per cent acidulated sodium fluoride mouth wash (pH 4)

was used three times a week by 31 dental students. At the end of a one year study period the experimental group showed no difference in dental caries in comparison to 15 control students which used an identical mouth wash but, which contained no fluoride.

Weisz¹⁰⁵⁻¹⁰⁶ conducted, in his private pedodontic clinic, a study in which the effectiveness on dental caries of 0.25 per cent sodium fluoride mouth wash was evaluated. The study was conducted for 10 years in which children ages 5 to 9 years used the fluoride mouth wash regularly twice a day after brushing the teeth with neutral dentifrice (fluoride-free dentifrice). When the treated patients (32 children) on whom observations were made for a minimum of two years, and up to a maximum of 10 years were compared with 60 children in the control group not using a mouth wash, the reduction in dental caries with the continuous use ranged from 80.0 to 90.0 per cent.

Torell and Siberg¹⁰⁷ studied the effectiveness on dental caries of using a 0.2 per cent sodium fluoride and a 0.2 per cent potassium fluoride mouth wash. The fluoride mouth wash was used for three minutes under supervision once every month by children ages 8 and 9 years. In the study no brushing was allowed immediately before rinsing the mouth with the fluoride solution. The reasoning given was that "Brushing the teeth with a toothpaste immediately before a mouthwash can not be recommended as precipitates between fluoride ions and components of certain toothpastes can hinder the the diffusion of fluoride ions into the enamel layers". The results

were evaluated according to the number of children having new proximal restorations in the incisor teeth during the one year study period. The group using the 0.2 per cent sodium fluoride mouth wash showed a decrease up to 27.0 per cent in new caries lesions on the proximal surfaces of the anterior teeth. The use of 0.2 per cent potassium fluoride mouthwash has no apparent effect on dental caries.

Another study by Torell and Ericsson⁷⁶ was conducted in which the unsupervised daily use of a 0.05 per cent sodium fluoride mouthwash was compared with the supervised use of a 0.2 per cent sodium fluoride mouth wash used every fortnight. At the end of a two year study period, subjects in Group A which used daily a 0.05 per cent sodium fluoride mouthwash under unsupervised condition showed a significantly greater reduction in dental caries than subjects in Group B which used a 0.2 per cent sodium fluoride mouthwash every fortnight. The reduction in terms of DMF surfaces was 49 per cent in Group A and 21.3 per cent in Group B. The results indicated that the frequency of application is important in obtaining better results even when 0.05 per cent sodium fluoride solutions are used.

STATEMENT OF PROBLEM

Statement of Problem

In reviewing the dental literature it was noted that the application of stannous fluoride containing prophylactic paste by trained personnel reduced the dental caries susceptibility between 20 to 50 per cent in both children and adults and in children residing in areas with optimal fluoride in the communal water supply. This method is time consuming, besides it need be conducted by trained personnel. There are approximately 15,000 hygienists in the United States,¹⁰⁸ and even if the supply of dental manpower is vastly increased the problem will not be solved because over 98 per cent of the population in the United States is affected by dental caries. The national average for new dental caries per child per year is about three new cavities in the permanent teeth.¹ This figure varies widely from one new cavity in some children up to 30 per year in others. Besides that the cost of repairing the result of dental caries is very high.

In order to obtain the effect of the anticariogenic prophylactic paste on mass basis in a short time with fewer trained personnel, self-application of the anticariogenic prophylactic paste by means of tooth-brush may be one answer to the problem. This hypothesis is tested in this thesis for its feasibility and effectiveness on dental caries using the self-application of the anticariogenic agents on six grade school children.

EXPERIMENTAL PROCEDURE

Experimental Procedure

In order to measure the feasibility and effectiveness on dental caries of the self-administration of the anticariogenic prophylactic paste, children ranging in age between 11 to 13 years were included in the study. DMF teeth and DMF surfaces were used to evaluate the effectiveness of the anticariogenic prophylactic paste. Greene and Vermillion's Oral Hygiene Index Simplified (OHI-S)¹⁰⁹ was used to measure oral debris and calculus, and Russel's Periodontal Index¹¹⁰ was used to measure the periodontal conditions.

After the approval of the clinical project by the School Board, Bloomington, Indiana, a letter was distributed to the parents of approximately 300 sixth grade children in nine different schools. The letter explained the importance of self-application of the anticariogenic prophylactic paste, as related to dental caries control, and asked their permission to allow their children to participate in the study. Only 23.3 per cent of the parents agreed to the project.

The children included in the study ranged in age from 11 to 13 years, and were divided into three study groups. All children received a thorough clinical and full mouth bite-wing radiographic examination initially and at six month intervals for one year study period. The examinations were performed by the author using portable dental equipment, artificial light, new explorers, mirrors and compressed air. The self-prophylaxis was performed at the same

time interval.

Children in Group I, included 23 children, who received only the clinical and radiographic examination and served as controls. Children in Group II, 21 children, received the self-prophylaxis of the anticariogenic paste. Children in Group III, 26 children, received the self-prophylaxis of the same anticariogenic paste used by Group II, and in addition were supplied with a dentifrice which contained 0.4 per cent SnF_2 and 10.0 per cent victamide for home use.

Group III will not be included in the data because it was not possible to obtain reliable information from the children regarding the use of the dentifrice. In addition, 50.0 per cent of the children claim they used Crest more than the dentifrice supplied to them.

Several different indices were used in order to obtain the data utilized in this study. Each index will be described briefly.

Indices for Determining Caries Experience

Both DMF teeth and DMF surfaces were used in order to evaluate the effectiveness of self-administration of the anticariogenic treatment, the following criteria for recording dental caries was used:

1. When there is no dental caries or restoration in any tooth surfaces, the tooth is recorded as sound (S).
2. Molars and pre-molars which were decayed to the gingiva were recorded as having five carious surfaces (5). In case

case of similarly decayed cuspids or incisors four carious surfaces (4) were used for recording purposes.

3. A missing permanent tooth which should have been present according to the age of the child is given a value of three DMF surfaces (3) for posterior teeth and two DMF surfaces (2) for anterior teeth.
4. The presence of full crowns and/or orthodontic bands were recorded by writing the word "crown" or "band".
5. Each tooth surface was recorded separately and was assigned a number as follows: Occlusal, 1; buccal, 2; distal, 3; lingual,⁴4; mesial, 5.

A scale was assigned to each lesion or restoration in order to provide information concerning the extension of the carious lesion, according to the following criteria: Lesion from incipient to $1/4$ of the surface is recorded as (a); lesion from $1/4$ to $1/2$ of the surface is recorded as (b); and, a lesion more than $1/2$ of the surface is recorded as (c).

The same criteria were used for restored surfaces except the letter (f) was added for identification of the restoration.

6. If one carious lesion and one restoration occur on the same surface, both are recorded and counted separately.

The data were computed in terms of total new DMF teeth and DMF surfaces for each child. No use was made of the severity of the lesions.

Index for Determining Oral Hygiene

The simplified oral hygiene index (OHI-S) reported by Greene and Vermillion was used.¹⁰⁹ The index consists of the sum of a debris score and a calculus score on six surfaces. The surfaces are selected from four posterior and two anterior teeth. The surfaces recorded in the maxillary arch are the buccal surfaces of the first molars, and the labial surface of the right central incisor. The surfaces recorded in the mandibular arch are the lingual surfaces of the first molars and the labial surface of the left central incisor. If any of the first molars are missing the second molar is substituted for it. In case of a missing central the opposite central is substituted for the designated lost tooth.

Each of the appropriate surfaces were examined for debris and calculus by passing a number 23 dental explorer over it.

The following scoring system was used:

Debris Score

- "0_____ No debris or stain present.
- 1_____ Soft debris covering not more than one-third of the tooth surface being examined or the presence of extensive stains without debris regardless of surface area.
- 2_____ Soft debris covering more than one-third but not more than two-thirds of the exposed surface.
- 3_____ Soft debris covering more than two-thirds of the exposed tooth surface."

Calculus Score

- "0_____ No calculus present.
- 1_____ Supragingival calculus covering not more than one-third of the exposed tooth surface being examined.
- 2_____ Supragingival calculus covering more than one-third but not more than two-thirds of the exposed surface, or the presence of individual flecks of subgingival calculus around the cervical portion of the tooth.
- 3_____ Supragingival calculus covering more than two-thirds of the exposed tooth surface or a continuous heavy band of subgingival calculus around the cervical portion of the tooth."¹⁰⁹

The debris and calculus scores for each patient are calculated separately. For example, if the six teeth have been scored for debris on a patient, these scores might be 1, 1, 2, 0, 1, 1. The total debris in this case is 6. The total is then divided by the number of teeth scored (six teeth). In this case the mean debris score for this patient would be 1.0.

The calculus score for that particular subject is calculated in the same way as the debris score. For example, the mean calculus score for this subject is 0.2.

The Oral Hygiene Index - Simplified for the patient is calculated by adding the debris and the calculus scores together. In this case it would be 1.2.

Index for Determining the Prevalence of Periodontal Diseases

Russell's periodontal index¹¹⁰ was used. The condition of the investing tissue is estimated individually for each fully erupted permanent tooth in the mouth.

The following criteria were used:

- 0 _____ Absence of visible inflammation of the soft tissue around the tooth.
- 1 _____ An overt area of inflammation in the free gingiva, but this area does not circumscribe the tooth.
- 2 _____ Inflammation completely circumscribing the tooth, but no apparent break in the epithelial attachment.
- 6 _____ Both gingivitis and periodontal pocket present but no interference with normal masticatory function.
- 8 _____ Advanced destruction with loss of masticatory function.

The periodontal index for an individual child is the arithmetic average of the scores of the teeth scored. For example, if the child examined only 26 permanent teeth were scored. The total periodontal score for that child happened to be 20. Then the periodontal index for that particular child is equal to 20 divided by 26, which is equal to 0.76.

The Self-Prophylaxis Procedure

Children in Groups II and III, after receiving the clinical and radiographic examination, conducted the self-prophylaxis as follows: The self-prophylaxis was given in any available room in the school. The children were divided into groups of six or eight at a time.

They were seated in a single row facing the hygienist. Each child was supplied with a disposable apron, a paper dish on which to place the paper cups and the paste, two paper cups (one full with tap water for rinsing and the other for spitting), small soft bristle tooth brushes (four rows and 10 tufts in each row) for applying the anticariogenic paste to the teeth while brushing, and napkins. Before the children were given the anticariogenic prophylactic paste, the hygienist conducted a demonstration on a suggested toothbrushing technique on herself and explained to the children the benefit of the self-prophylaxis by the anti-cariogenic agents in protecting their teeth against dental caries. Also she explained to them that teeth should be brushed the way they grow so they will understand and follow the suggested procedure. Both the facial and lingual surfaces in addition to the occlusal surface are to be brushed. Each area should be brushed a minimum of at least 10 times. The hygienist demonstrated to the children how to place the brush as high as possible in the vestibule in the maxillary arch, and as low as possible in the mandibular arch, and then the brush is moved slowly occlusally with a rolling motion. The occlusal surfaces are brushed in a scrubbing motion. The hygienist asked the children to practice brushing in her presence before she supplied them with the prophylactic paste. This explanatory demonstration was given at the first meeting. At six month intervals the hygienist re-evaluated their brushing procedure again before supplying

the prophylactic paste for the new treatments.

The anticariogenic prophylactic paste was mixed fresh before distributing it to the children. It consisted of stannous fluoride (SnF_2), sodium monobasic phosphate (NaH_2PO_4), and zirconium silicate (ZrSiO_4). The concentration of both stannous fluoride and sodium monobasic phosphate in the final mix is 9.0 per cent.

The mixing was performed in the following way: First, 2.7 grams of stannous fluoride was dissolved in 3.8 cc distilled water, to which 2.7 grams sodium monobasic phosphate was added and mixed well until a fluffy white paste resulted. Then 20.8 grams of flavored zirconium silicate was added and again mixed well. This 30 grams of stannous fluoride-phosphate prophylactic paste is sufficient for six children. Each child was given approximately five grams of the anticariogenic paste.

The children were asked not to swallow while brushing, but spit any time they wanted. They were not allowed to rinse until the hygienist asked them to do so. The hygienist asked the children to dip the tip of the bristles of their brushes in the paste and she checked that each child had an adequate amount of the paste on his brush.

The brushing of different segments was performed in the following order: The occlusal surface of right maxillary teeth, the occlusal surface of left maxillary teeth, then occlusal surface of left mandibular teeth, and the occlusal surface of right mandibular teeth.

The first rinsing was allowed after all occlusal surfaces were brushed. They were then asked to brush the facial surface of all maxillary teeth, starting from right to left. After that to brush the lingual surface of all the maxillary teeth also from right to left. The second rinsing was allowed after brushing the facial and lingual maxillary surfaces.

The facial surfaces of all mandibular teeth, and after that the lingual surfaces of all mandibular teeth, were brushed in the same way, and then the third rinse was allowed. While brushing, the hygienist counted 10 for each segment. In-between brushings the children were asked to dip their brushes in the paste in order that always the children will have sufficient amount of the paste on their brushes. After the third rinse each child was examined by the hygienist using tongue depressor for any residual paste in the mouth and to see if they did a thorough job of removing debris. The time required for the entire procedure was between 20 to 25 minutes.

Children of this age can follow the instructions of the hygienist very well and there was no problems in following the technique explained to them by her.

Children in Group III who received the dentifrice were supplied one tube per month, the first dispensed after the self-prophylaxis. Before school was dismissed they were supplied with three additional tubes.

At six month intervals clinical and radiographic examinations

were repeated, with self-prophylaxis performed by Groups II and III following the same procedure as described previously.

At the one year interval the three groups received only the clinical and radiographic examinations.

DATA

Data

A comparison of the dental caries findings both for DMF teeth and DMF surfaces in all of the subjects in Group I (control) and Group II (self-prophylaxis) at the initial examination is found in Table I. It is shown that there is no significant difference between the two groups both for DMFT and DMFS. A comparison of the oral hygiene and periodontal scores for the same subjects at the initial examination is found in Table II, which shows there is no significant differences between the two groups for both oral hygiene and the periodontal score.

The dental caries increments of both Groups I and II during the six month interval for subjects present at both examinations is found in Table III. Group I (control), which included 22 children who were present initially and at the six month re-examination had a mean caries increment of 3.55 new DMF teeth and 7.32 new DMF surfaces. Group II (self-prophylaxis) which included 19 children who were present initially and at the six month re-examination had a mean caries increment of 1.37 new DMF teeth and 3.79 new DMF surfaces. This represents a reduction in dental caries of 61.4 and 48.2 per cent in terms of DMF teeth and DMF surfaces indices, respectively, when compared to the control group. These reductions are significant as shown by their low probabilities.

Table IV shows the mean change in the oral hygiene and periodontal scores of subjects in Group I (control) and Group II (self-prophylaxis) who were present initially and at the six month re-examination. Group I

had a mean change in the oral hygiene score equal to +0.13 increase and +0.15 increase in the periodontal score. This represents 8.9 and 17 per cent increase in oral hygiene and periodontal scores, respectively, when the scores within the group are compared. These changes are not statistically significant.

Group II had a mean change in oral hygiene score equal to -0.60 and in periodontal score equal to -0.43. These changes represent a 37 and 46 per cent decrease in the oral hygiene and periodontal scores, respectively, when the scores within the group compared. These changes are significant as shown by their low probabilities.

Table IV also shows the significance in changes of oral hygiene and periodontal scores of Group II (self-prophylaxis) as compared to Group I at the six month period. These changes are significant as shown by their low probabilities for both the oral hygiene and periodontal scores.

A comparison of the dental caries increments during one year period is shown in Table V. Group I (control) which included 19 children present initially and for the one year re-examination, had a mean caries increment of 4.95 new DMF teeth and 10.84 new DMF surfaces. Group II (self-prophylaxis) which included 12 children present both initially and for the one year re-examination, had a mean caries increment of 1.33 new DMF teeth and 4.50 new DMF surfaces. This represents a reduction in dental caries of 73.1 and 58.5 per cent for DMF teeth and DMF surfaces, respectively, when compared to the control group. These differences are significant as shown

by their low probabilities.

Table VI shows the dental caries increments of different tooth surfaces. During the one year period Group I had a mean caries increment of 3.52, 4.79, 1.00 and 1.53 in occlusal, proximals, buccal and lingual surfaces, respectively. Group II had a mean dental caries increment of 0.00, 3.75, 0.41 and 0.33 in occlusal, proximal, buccal and lingual surfaces, respectively. This represents a 100.0, 21.7, 59.0 and 78.4 per cent reduction in occlusal, proximal, buccal and lingual surfaces, respectively, as compared to the control group.

Table VII shows the changes in oral hygiene and periodontal scores of the two groups at the one year period. Group I (control) had a mean change in oral hygiene score equal to +0.12 and a mean change in periodontal score equal to -0.06. This represents an increase of eight per cent in oral hygiene score and a decrease of six per cent in periodontal score. These changes are not significant. The children in Group II (self-prophylaxis) had a mean change in oral hygiene score equal to -0.66 and -0.43 in periodontal score. This represents a 40 and 42 per cent decrease in oral hygiene score and periodontal score, respectively, within the group. These changes are significant as shown by their low probabilities.

Table VII also shows the significance in changes of oral hygiene and periodontal scores of Group II (self-prophylaxis) as compared to Group I (control) at the one year period. The changes in the oral hygiene score of the self-prophylaxis group is significant as shown by

its low probability as compared to the control. When the changes in the periodontal score of the self-prophylaxis group was evaluated, the change is not significant as compared to the control group.

TABLES

TABLE I
Comparison of Study Groups at Initial Examination
According to Age, Number of Permanent Teeth and DMFT, DMFS

Group	No. of Students Initial	Age Range	Mean DMFT	Mean DMFS	Mean Total No. of Permanent Teeth	Significance Between Groups					
						DMFT		DMFS			
						T	P	T	P		
I Control	23	11.0 -13.04	8.78	0.99*	14.39	2.04*	14.39	0.31	<0.8	1.37	<0.2
II Self- Prophylaxis	21	11.04-13.02	9.52	0.79*	14.67	1.24*	14.67				

*Standard error of mean

TABLE II

Comparison of Study Groups at Initial Examination According
to Oral Hygiene and Periodontal Scores

Group	No. of Students Initial	Mean OHI-S		Mean Perio		Significance Between Groups			
						OHI-S T	P	Perio T	P
I Control	23	1.45	0.17*	0.82	0.14*	1.58	< 0.5	0.52	< 0.7
II Self- Prophylaxis	21	1.56	0.17*	0.93	0.15*				

*Standard error of mean

TABLE III

A Comparison of Dental Caries Increments During Six Month Period in Two Groups of Children
Receiving Either Examination Only or Self-Application of Anticariogenic Prophylactic Paste

Group	No. of Children	Mean DMFT (initial)	Mean DMFT (increment)	Mean DMFS (initial)	Mean DMFS (increment)	% Difference		P _t	
						DMFT	DMFS	DMFT	DMFS
I Control	22	8.82	1.06*	3.55	14.55	2.19*	7.32		
II Self- Prophylaxis	19	9.66	0.77*	1.37	14.83	1.26*	3.79	61.4	48.2
								t=2.45 < 0.02	t=2.06 < 0.05

*Standard error of mean

TABLE IV

A Comparison of Oral Hygiene and Periodontal Changes During
Six Months Period in Two Groups of Children Receiving Either Examination
Only or Self-Prophylaxis of Anticariogenic Prophylactic Paste

Group	No. of Children	Mean OHI-S Initial	Mean OHI-S Change	% Change	Mean Perio Initial	Mean Perio Change	% Change	Significance Within Group P_t		Significance Between Groups P_t			
								OHI-S	Perio	OHI-S	Perio		
I Control	22	1.45	0.18*	+0.13	8.9 (increase)	0.88	0.15*	+0.15	17 (increase)	t 0.58 p <0.6	t 0.58 p <0.6		
II Self- Prophylaxis	19	1.62	0.18*	-0.60	37 (decrease)	0.94	0.11*	-0.43	46 (decrease)	t 2.56 p <0.02	t 2.76 p <0.02	t 4.91 p <0.001	t 2.70 p <0.01

*Standard error of mean

TABLE V

A Comparison of Dental Caries Increments During One Year Period in Two Groups of Children Receiving
Either Examination Only or Self-Application of Anticariogenic Prophylactic Paste

Group	No. of Children	Mean DMFT (Initial)		Mean DMFT (Increments)		Mean DMFS (Initial)		Mean DMFS (Increments)		% Difference		P _t	
										DMFT	DMFS	DMFT	DMFS
I Control	19	8.74	1.34*	4.95		14.37	2.83*	10.84		-	-		
II Self- Prophylaxis	12	9.66	0.92*	1.33		14.38	1.85*	4.50		73.1	58.5	t=3.89 < 0.001	t=2.88 < 0.01

Standard error of mean

TABLE VI

A Comparison of Dental Caries Increments of Different Tooth Surfaces During One Year Period in Two Groups of Children Receiving Either Examination Only or Self-Prophylaxis of Anticariogenic Prophylactic Paste

Group	No. of Children	Mean Surface Initial		Mean Surface Change	% Reduction	Significance t	p
I Control	19	Occlusal 6.37	0.28*	3.52			
		Proximal 4.21	1.61*	4.79			
		Buccal 1.42	0.06*	1.00			
		Lingual 1.26	0.18*	1.53			
II Self- Prophylaxis	12	Occlusal 7.25	0.27*	0.00	100	4.69	< 0.001
		Proximal 3.08	0.90*	3.57	21.7	1.37	< 0.2
		Buccal 1.42	0.10*	0.41	58.0	1.42	< 0.2
		Lingual 1.42	1.16*	0.33	78.4	3.33	< 0.01

* Standard error of mean

TABLE VII

A Comparison of Oral Hygiene and Periodontal Changes During
One Year Period in Two Groups of Children Receiving Either Examination Only
or Self-Prophylaxis of Anticariogenic Prophylactic Paste

Group	No. of Children	Mean		Mean		Mean		Mean		Significance		Significance	
		OHI-S		OHI-S		Perio		Perio		Within		Between	
		Initial	Change	Change	% Change	Initial	Change	Change	% Change	Group	P _t	Groups	P _t
										OHI-S	Perio	OHI-S	Perio
I Control	19	1.52	0.20*	+0.12	8 (increase)	0.92	0.17*	-0.06	6 (decrease)	t 0.45	t 0.29		
										p <0.1	p <0.9		
II Self- Prophylaxis	12	1.66	0.23*	-0.66	40 (decrease)	1.03	0.15*	-0.43	42 (decrease)	t 2.35	t 2.62	t 3.80	t 1.6 ^a
										p <0.05	p <0.05	p <0.01	p <0.2

Standard error of mean

DISCUSSION

Discussion

The objective of this study was to investigate the feasibility of the self-application of a new anticariogenic prophylactic paste. The effect on oral cleanliness and periodontal health has also been considered.

The dental caries data indicates a significant reduction in dental caries at both the six month and one year period when evaluated by either the DMF teeth or the DMF surfaces index. These results are in agreement with several other clinical studies in which the stannous fluoride prophylactic paste was applied in the routine way by the dentist or dental hygienist in determining its anticariogenic effectiveness in both children and adults in fluoride and non-fluoride area.^{25-28, 48-52}

Also these results confirm the clinical studies in which the self-application of fluoride solutions (sodium fluoride, sodium monofluorophosphate and ferric fluoride) by means of toothbrush was utilized for its anticariogenic effect.^{76, 94-96, 98-102}

In this research the stannous fluoride prophylactic paste is used in the self-administration procedure, by the children. The dental caries data show that at one year period the children received the self-application of the stannous fluoride-phosphate prophylactic paste had 73.1 and 58.5 per cent reduction in terms of DMF teeth and DMF surfaces, respectively.

In previous clinical studies which were conducted by other investigators in determining the anticariogenic effectiveness of stannous fluoride prophylactic paste when applied in the routine

rubber-cup procedure by the dentist or dental hygienist, the results showed 20 to 50 per cent reduction in dental caries.

If these results compared to the results obtained in this research, the self-administration of the stannous fluoride-phosphate prophylactic paste is shown more effective in reducing dental caries than stannous fluoride prophylactic paste alone given by the trained personnel. It has been shown also by Muhler and co-workers⁵⁶ in vitro and in vivo that stannous fluoride-phosphate prophylactic paste is 50.0 per cent more effective in reducing enamel solubility than stannous fluoride prophylactic paste alone.

Muhler and co-workers¹¹¹ in a clinical dental caries study have compared the anticariogenic effect of topically applied stannous fluoride solution, stannous fluoride-phosphate system, and sodium-phosphate system. The addition of sodium monobasic phosphate to the stannous fluoride solution increases the effectiveness of the stannous fluoride by about 50.0 per cent with reduction of 84.9 and 80.1 per cent in the DMFT and DMFS indices during the first six months of the study. The sodium fluoride-phosphate system was found to be comparable in effectiveness to stannous fluoride treatment alone. The results at the twelve month period are similar to those obtained at six months. The results of these studies taken collectively show that the efficacy of stannous fluoride is markedly improved by the addition of sodium monobasic phosphate.

The effect of the self-application of the stannous fluoride-phosphate prophylactic paste on the different tooth surfaces at one

year period was shown in Table IV. These results are 21.7, 100.0, 59.0 and 78.4 per cent reduction in dental caries of proximal, occlusal, buccal and lingual surfaces, respectively. It is evident from the above results that there is better protection afforded to the occlusal surfaces than the proximal surfaces. In the study conducted by Muhler, et al⁶² the effect of stannous fluoride dentifrice on different tooth surfaces, the results showed 100.0, 70.0 and 26.0 per cent reduction in dental caries of proximal, buccal, and occlusal surfaces, respectively. In this study these results could be due to two reasons. First the children could be brushing the occlusal surfaces better than the other surfaces. In fact, they were instructed to brush all occlusal surfaces first and then the others. Secondly, in the routine way of applying stannous fluoride prophylactic paste by the dentist or dental hygienist, after polishing the buccal and lingual surfaces they use unwaxed dental floss to clean and polish the proximal surfaces and to carry the stannous fluoride prophylactic paste proximally.¹¹² While in the self-application of the prophylactic paste the children did not use the dental floss for interproximal surfaces and hence the bristles of the brush do not get into the proximal area as effectively as the dental floss.

In a study conducted by Foster¹⁰³ to evaluate the feasibility of self-prophylaxis with stannous fluoride prophylactic paste versus routine rubber-cup applied prophylaxis by trained personnel, he reported that "In fact it frequently appeared that the occlusal surfaces were missed completely by the dental technicians. When the patients brushed this occurrence was rare".

From an examination of the oral hygiene and periodontal data it was found that there is a direct relationship between the oral hygiene and periodontal scores. This relationship has been shown by other investigators^{109, 113-115} also. Children in the self-prophylaxis group showed a significant improvement in both the oral hygiene and periodontal score at both the six months and one year periods when compared to their initial scores. This improvement could be due to the instructions given to the children in toothbrushing twice during the one year study period. Also, after the children completed the self-application of the prophylactic paste, they were asked to keep the toothbrushes for home use and follow the same brushing procedure with their own dentifrices. It could be that these instructions and the clinical examination by the dentist motivating the children to improve their oral hygiene.

This is comparable to the findings of a study conducted by Christman.¹¹⁶ In his study the group receiving the self-prophylaxis and therapeutic dentifrice in addition to the clinical and radiographic examination showed improvement on their oral hygiene at the end of one year study period. The children in the control group showed no significant changes in either the oral hygiene or periodontal score at six month period as compared to their initial scores.. At the one year period the increase in oral hygiene score is less than that at six month period. There is no significant improvement in the periodontal score at the one year period as compared to their initial scores. These results demonstrate the relation-

ship between the oral hygiene score and the periodontal score. When the oral hygiene score of the control group at one year period is less than that at six month period, there is also changes in the periodontal score at one year which is lower than the score at six month period.

During the clinical examination it was noticed that a few small number of the children had dental calculus, so no attempt was made to separate the oral hygiene index into its two components, debris index and calculus index. The mean oral hygiene score shown in the data represents the sum of debris score and a calculus score. Besides it has been concluded by Greene and Vermillion¹¹³ that "the oral hygiene index was more closely associated with the periodontal score than were either of its two component indexes (debris and calculus)".

The aim of preventive dentistry is to provide a mass benefit of the available anticariogenic agents to a large number of people in a short time interval, and at a low cost. In this study it was noticed that up to eight children (which is the maximum number of children at a time instructed) at a time could be instructed in the self-application of the anticariogenic prophylactic paste in 20 to 25 minutes. In the routine rubber-cup method of applying the anticariogenic prophylactic paste by the dentist or dental hygienist, in this time period (20 to 25 minutes) only one patient could receive the treatment. In my opinion, in this age group (11 to 13 years) up to 20 children at a time could be easily dealt with

and supervised for applying the self-prophylaxis of the anticariogenic prophylactic paste in 20 to 25 minutes. Especially, if two hygienists worked together one giving instructions and the other supervising the children. In a study which is now in progress in Ft. Wayne, Indiana, up to 1,700 school children simultaneously performed the self-application of the anticariogenic prophylactic paste. The instructions for the proper manner of toothbrushing were given by the local dentists and dental hygienists who were previously instructed by Indiana University personnel. The actual brushing was performed under the supervision of the school teachers as well as the dentists and hygienists.¹¹⁷ Besides the number of children in the group instructed at a time in applying the self-prophylaxis, the directions given to the children are important also, e.g., seating of the children. If the children are seated facing each other, they have a tendency to copy each other and become confused regarding their right and left sides for brushing instead of following the correct instructions given by the hygienist.

This age group of children are very cooperative and could follow the instructions easily. The children were examined by the hygienist immediately after the self-application of the stannous fluoride treatment was completed for the effect of the paste on the oral tissue. None of the children showed any apparent effect i.e. blanching of the gingiva or redness. In regard to the test, very few of the children complained of the taste of the paste. None of the children vomited during or after the self-application.

By means of this simple, safe, quick, and low cost method, large number of people could be reached and provided with the benefit of the available anticariogenic agents in controlling dental caries.

Before this method of the partial control of dental caries could be considered as a successful procedure, more clinical studies should be conducted to evaluate its effectiveness and utility.

SUMMARY AND CONCLUSION

Summary and Conclusion

The known preventive measures, beside water fluoridation, for the partial control of dental caries have to be conducted by the dentist or dental hygienist. Due to the high ratio of dentist to population in the United States and the small number of hygienists available to conduct such treatments, with the increasing backlog of dental diseases makes the preventive treatment program available to only a small number of people. Beside this, the cost of the treatment, and the time needed by the dentist or the dental hygienist, retards its use.

In reviewing the literature it was shown that stannous fluoride prophylactic paste when applied in the routine way by the dentist or dental hygienist in fluoride and non-fluoride areas to both adults and children provides a 20 to 50 per cent reduction in dental caries.

The idea of self-application of stannous fluoride prophylactic paste by means of a toothbrush was investigated in this study. Children of six grades in nine schools of Monroe County were included in the study. The age of the children ranged between 11 to 13 years. Children in Group I (control) included 22 children who were present initially and at six month re-examination, and 19 children at the one year re-examination. These children received only clinical and radiographic examination initially and at the six month interval. Children in Group II (self-prophylaxis) included 19 children initially and at six month re-examination, and 12 children at the

one year re-examination period. These children received the clinical and radiographic examination and the self-application of the stannous fluoride-phosphate prophylaxis paste by means of the toothbrush initially and at six month interval. The group receiving only the clinical and radiographic examination (Group I) showed a mean caries increment of 3.55 new DMF teeth and 7.32 new DMF surfaces at six month period. At one year period they showed a mean caries increment of 4.95 new DMF teeth and 10.84 new DMF surfaces. The children receiving the self-application of the stannous fluoride-phosphate prophylactic paste had 1.37 new DMF teeth and 3.79 new DMF surfaces at six month period. This represents a significant reduction of 61.4 and 48.2 per cent in terms of DMF teeth and DMF surfaces, respectively, as compared to the control group.

At the one year period, the children in the self-prophylaxis group showed a 1.33 new DMF teeth and 4.50 new DMF surfaces. This represents a significant reduction of 73.1 and 58.5 per cent in terms of DMF teeth and DMF surfaces, respectively, in comparison to the control group. When the effect of the stannous fluoride prophylactic paste on different tooth surfaces at one year period was analyzed, the results showed there was 21.7, 100.0, 59.0 and 78.4 per cent reduction in dental caries of proximal, occlusal, buccal and lingual surfaces, respectively.

The oral hygiene and periodontal conditions of all children was also evaluated initially and at six month interval. The

control group showed no significant effect for either the oral hygiene score or periodontal score, respectively, at six month period as compared to their initial score. At the year period they showed no difference as compared to their initial scores.

The self-prophylaxis group at six month period showed a significant decrease of 37.0 and 46.0 per cent in oral hygiene score and periodontal score as compared to their initial scores. At one year period they showed 40.0 and 42.0 per cent significant improvement in the oral hygiene score and periodontal score, respectively, as compared to their initial scores.

The finding of this study indicates that partial control of dental caries could be achieved through the self-application of the stannous fluoride anticariogenic prophylactic paste by means of a toothbrush.

Beside the effect on dental caries, the results showed that the thorough instruction and practice of proper toothbrushing by the children during the self-prophylaxis procedure has a marked effect on motivating them to improve their oral hygiene and periodontal conditions. The self-prophylaxis procedure could be considered a real progress in preventive dentistry. It could be expected to provide the benefit of the available anticariogenic agents to larger populations in short time at a very low cost and with few number of trained personnel.

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ABSTRACT

Abstract

Self-Application of an Anticariogenic Prophylaxis Paste as a Technique for the Partial Reduction of Dental Caries Performed on a Mass Treatment Basis

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It has been shown repeatedly that the partial control of dental caries is possible through the use of fluoride compounds, either systemically or topically. Almost all the different treatments, beside water fluoridation, need be conducted by the dentist or dental hygienist. The high ratio of dentist to population, the cost and the time factor limits their uses. The demand for a new method to control dental caries was utilized in which the benefit of the available anticariogenic agents could be given on mass scale, with low cost and which could be conducted with fewer trained personnel.

A clinical study was designed to evaluate the feasibility and effectiveness of self-application of a new anticariogenic prophylactic paste on dental caries by means of toothbrush. The self-prophylaxis was conducted each six months, by six-grade school children under supervision after thorough demonstration on proper toothbrushing by the hygienist.

After one year the results showed that the self-application of the anticariogenic prophylactic paste resulted in 73.1 and 58.5 per cent reductions in DMFT and DMFS, respectively. Also, the instruction and practice of proper toothbrushing by the children twice a year motivated them to improve their oral hygiene and periodontal condition by 40.0 and 42.0 per cent, respectively.

It appears that the partial control of dental caries achieved on mass basis, at low cost and conducted by fewer trained personnel is as effective as the treatment given by the trained personnel.